IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. WALMART INC. AND WAL-MART STORES EAST, LP, Defendants.	)	Jury Trial Demanded Civil Action No. 1:20-cv-01744-CFC

AMENDED COMPLAINT

TABLE OF CONTENTS

INTRODUCTION

1. The United States of America brings this civil enforcement action against Walmart for violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "CSA"), 21 U.S.C. §§ 801 *et seq*.

2. The CSA prohibits the diversion of controlled substances, including prescription opioids, by regulating every participant in the supply chain for those substances, from manufacturers to wholesale distributors to retail pharmacies. Diversion occurs when a controlled substance is unlawfully used, transferred, or possessed, as a result of an illegal prescription, theft, or sale in the illicit marketplace. Under the CSA, every participant in the supply chain bears responsibility for preventing the diversion of controlled substances.

3. Walmart is one of the country's largest pharmacy chains. It operates more than 5,000 pharmacies at Walmart-branded and Sam's Club-branded retail stores nationwide. Through its pharmacies, Walmart dispenses controlled substances to customers. In addition, until 2018, Walmart acted as a wholesale distributor of controlled substances for its own pharmacies.

4. As both a pharmacy and a distributor, Walmart assumed critical gatekeeping responsibilities under the CSA. At two stages—when deciding whether to fill individuals' prescriptions for controlled substances and when deciding whether to fill its pharmacies' wholesale orders for controlled substances from its distribution warehouse—Walmart was required by the CSA to take steps to prevent diversion.

5. Yet, for years, as the opioid epidemic ravaged the country, Walmart failed to fulfill those responsibilities. Predictably, Walmart's violations of the CSA had disastrous results, allowing individuals to abuse or misuse controlled substances to the detriment of themselves and

their communities. And given the nationwide scale of those violations, Walmart's failures helped to fuel a national opioid crisis.

6. Accordingly, the United States seeks both civil penalties and appropriate injunctive relief under the CSA.

A. As a pharmacy, Walmart violated the rules for dispensing controlled substances.

7. Walmart is permitted to dispense controlled substances at its thousands of pharmacies only under the authority granted it by the Drug Enforcement Administration ("DEA"). By seeking and obtaining registrations from DEA to dispense controlled substances, Walmart assumed the associated obligations of a dispenser of controlled substances.

8. Because dispensers are the final step in the supply chain before individuals receive controlled substances, and thus the last line of defense in preventing diversion, the CSA and its implementing regulations require pharmacies to comply with certain legal requirements before filling controlled-substance prescriptions. A foundational requirement is that the pharmacy may dispense controlled substances only pursuant to a valid prescription. A prescription must satisfy two requirements to be valid. It must be issued (1) for a legitimate medical purpose and (2) by a medical practitioner acting in the usual course of his or her professional practice. *See* 21 C.F.R. § 1306.04(a). Another critical requirement is that pharmacists must adhere to the usual course of professional pharmacy practice in filling a prescription for controlled substances. *See id.* § 1306.06. The usual course of professional pharmacy practice requires identification and resolution of "red flags"—signs indicating the potential invalidity of a prescription—before filling a prescription. And if a pharmacist resolves the red flags, the usual course of professional pharmacy practice requires the pharmacist to document the resolution.

9. Through the actions of both its compliance team members and its pharmacists,

Walmart violated these two requirements.

10. First, Walmart filled invalid prescriptions both through the knowing actions of individuals on its compliance team and through the knowing actions of its pharmacists.

11. Members of Walmart's compliance team knew that certain prescribers were operating as "pill mills"—prescribing controlled substances outside the usual course of professional practice—and yet Walmart filled invalid prescriptions written by those prescribers. Members of the compliance team knew of the egregious conduct of these prescribers because Walmart's own pharmacists reported that conduct to the compliance team through thousands of "refusal-to-fill" forms, which Walmart collected and maintained as a result of a 2011 administrative enforcement action by DEA. Pharmacists also reported egregious conduct by pill-mill prescribers to the compliance team in emails seeking guidance about whether to fill those prescriptions. From these reports, compliance team members learned that the reported prescribers were "known pill mills," did "not practice real medicine," had "horrendous prescribing practices," and continually issued high-dose controlled-substance prescriptions for many individuals.

12. Those same compliance team members also knew that the thousands of reports they received from pharmacists were symptoms of an opioid epidemic that was broad and persistent, making it inevitable that Walmart pharmacies nationwide would continue to receive invalid prescriptions from known pill-mill prescribers. Indeed, the thousands of refusal-to-fill forms showed that Walmart pharmacies, in fact, did continue to receive thousands of invalid prescriptions from the same pill-mill prescribers.

13. Yet the compliance team members who knew about the reported conduct of pill-mill prescribers took actions that they knew would result, and did result, in Walmart pharmacies

filling thousands of invalid prescriptions written by those same prescribers. Compliance team members chose for years, for example, not to make available to pharmacists the significant derogatory information the team members regularly received about the pill-mill prescribers, forcing pharmacists to make, without that critical information, decisions about whether to fill prescriptions. The team members also decided against instituting controls that would have prevented, and instead adopted policies that further led to, the filling of invalid prescriptions by prescribers they knew were pill mills.

14. These choices, and others, reflected the compliance team's prioritization of other goals over compliance with the CSA. As B.N., a director on the compliance team, acknowledged in an email, rather than analyzing the refusal-to-fill reports, the compliance team viewed "[d]riving sales and patient awareness" as "a far better use of our Market Directors and Market manager's time."

15. Walmart pharmacists also filled prescriptions they knew were invalid. These pharmacists knew the prescriptions were invalid because they were written by prescribers known by the pharmacists to be acting outside the usual course of professional practice or the prescriptions had obvious red flags related to the prescription itself, the prescriber, the customer, or a combination of factors. Indeed, some Walmart pharmacies filled prescriptions written by prescribers whom those same pharmacies previously had reported as being pill-mill prescribers or showing red flags so obvious that the prescriptions previously had been refused by another Walmart pharmacy.

16. Second, Walmart pharmacists filled prescriptions while acting outside the usual course of professional pharmacy practice, which requires that pharmacists identify and resolve all red flags before dispensing any controlled substance. Contrary to the usual course of

professional pharmacy practice, Walmart pharmacists filled invalid prescriptions without identifying and resolving obvious red flags. Further, to the extent that Walmart pharmacists resolved red flags, they did so without documenting the resolution.

17. As a result of the failures of Walmart compliance team members and pharmacists to take seriously the gatekeeping duties mandated by the CSA, from June 26, 2013, to the present (hereinafter referred to as the "Dispensing Violations Period"), Walmart repeatedly violated the dispensing requirements identified in 21 C.F.R. §§ 1306.04(a) and 1306.06. For each violation, Walmart is liable for a civil penalty. *See* 21 U.S.C. § 842(c)(1). The Court also may grant injunctive relief to address and restrain further violations. *See* 21 U.S.C. § 843(f).

B. As a distributor, Walmart violated its duty to report suspicious orders of controlled substances.

18. As a distributor, Walmart had a basic obligation to detect suspicious orders placed by its own pharmacies for controlled substances and to report those orders to DEA. Distributors of controlled substances are required by the regulations implementing the CSA to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and "shall inform" DEA of those suspicious orders "when discovered." *See* 21 C.F.R. § 1301.74(b). Thus, a distributor must itself identify suspicious orders and report them to DEA. This requirement protects against diversion by requiring distributors to monitor pharmacies for warning signs of such misconduct.

19. DEA's regulations provide that suspicious orders "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id*. In other words, orders that are unusual in one or more of those three ways—size, pattern, or frequency—are deemed "suspicious orders," and a distributor must report them. The regulation does not limit "suspicious orders" to those three categories, however. It states, non-exclusively,

that suspicious orders "include" those categories.

20. Because Walmart acted as its own distributor for controlled substances, it had a special advantage: Walmart had extensive data and other information that gave it the ability—had it wanted—to evaluate orders for controlled substances.

21. But for years, Walmart maintained a wholly inadequate system for reporting suspicious controlled-substance orders placed by its pharmacies, routinely failing to report orders that exhibited unusual frequency, deviated from the normal ordering pattern, or were of unusual size. For example, members of the compliance team complained at various times that its system for receiving and shipping orders was so fast that it allowed only "limited time for evaluation" of each order, that there were "too many orders to review each line [of alerts] in detail," and that Walmart's system "did not allow alerted orders to be 'held' pending evaluation."

22. Walmart's compliance team knew that Walmart could face penalties and other potential enforcement for not complying with its obligation to report suspicious orders. In 2014, Walmart knew it needed to modify its system to "avoid DEA enforcement as a result of non-compliance with 21 CFR 1301.74(b)," but it then opted for years not to spend the time, money, and effort needed to bring its system into compliance with the law.

23. Because Walmart prioritized speed over compliance, it failed to report at least hundreds of thousands of suspicious orders that it received from its pharmacies. Indeed, between June 26, 2013, and November 29, 2017 (hereinafter referred to as the "Distribution Violations Period"), Walmart shipped an estimated 37.5 million controlled-substance orders to its pharmacies but reported only 204 suspicious orders to DEA. By comparison, during the same time period, Walmart's back-up distributor, McKesson Corporation ("McKesson"), which filled orders only when Walmart could not and which therefore shipped far fewer orders, reported to

DEA more than 13,000 suspicious orders from Walmart pharmacies.

24. Even when Walmart did identify a suspicious order, it often already had shipped the order and chose not to have it shipped back or to report it. As a Walmart Senior Manager for Logistics observed in an email, "if we see an issue that suggests the product shouldn't have shipped, we just leave it at the store and let it enter the market," even though having the order shipped back "feels like the more socially responsible approach…."

25. Walmart's inadequate suspicious-order monitoring program contributed to its failure to stop diversion of controlled substances at its pharmacies and created a major obstacle to efforts to combat the opioid epidemic. Had the company identified and investigated its extraordinary number of suspicious orders, it could have stopped the pharmacies that were placing those orders from unlawfully filling controlled-substance prescriptions or otherwise contributing to the diversion of controlled substances.

26. Each time Walmart failed to comply with its legal obligation to report a suspicious order, it violated the CSA. Pursuant to 21 U.S.C. § 842(a)(5), it is unlawful for a distributor to refuse, or negligently fail, to make or furnish reports, notifications, or information that are required under the CSA. For each violation of 21 U.S.C. § 842(a)(5), Walmart is liable for a civil penalty. *See* 21 U.S.C. § 842(c)(1)(A), (B).

C. Walmart systematically violated the CSA even as it recognized the opioid epidemic gripping the nation.

27. During the very period when Walmart was systematically failing to comply with its legal responsibilities both as a dispenser and as a distributor to protect against the diversion of prescription drugs, the opioid epidemic in the United States was exploding.

28. Between 1999 and 2020, more than 263,000 people died in the United States from overdoses involving prescription opioids.

https://www.cdc.gov/drugoverdose/data/prescribing/overview.html (last visited Aug. 24, 2022). "Overdose deaths involving prescription opioids nearly increased by five times from 1999 to 2020." *Id.*

29. In 2016 alone, opioid overdoses caused more than 42,000 deaths—more than any previous year on record. U.S. Department of Health and Human Services, *About the Epidemic*, https://www.hhs.gov/opioids/about-the-epidemic (last visited Oct. 26, 2020). An estimated 40 percent of those deaths—more than 16,800—involved prescription opioids. *Id.*

30. Indeed, there were so many opioid-related deaths in 2015 and 2016 that the epidemic caused U.S. life expectancy to decrease in both years. *CDC in Action: 2018 Response to the Opioid Crisis*, https://www.cdc.gov/opioids/pdf/Overdose-Snapshot-2018_Final_508.pdf (last visited Sept. 8, 2022). This was the first two-year decrease in life expectancy in over half a century. *See* National Vital Statistics Reports, Vol. 68, No. 7, June 24, 2019, at Table 19, https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_07-508.pdf (last visited Sept. 8, 2022).

31. As the federal judge presiding over the national prescription opiate multidistrict litigation recently found,

> [R]ates of opioid addiction, overdose, and death continue to rise alarmingly, and many citizens who were once productive taxpayers have died or become unable to work. Many have become a drain on the public fisc. First responders and medical professionals are stretched thin responding to overdoses and attempting to meet the vast demand for effective drug treatment. Families bear the weight of lost parents, siblings, children, and other caregivers. . . . Schools have to teach children who are at higher risk of developing substance use disorder because they were exposed to [opioid use disorder] in their home, or themselves suffer from Neonatal Opioid Withdrawal Syndrome ("NOWS") or Neonatal Abstinence Syndrome ("NAS").

32. Walmart recognized the growing and deadly opioid epidemic but nevertheless routinely ignored the very legal requirements that could have helped to stem the epidemic.

PARTIES

33. Plaintiff is the United States of America.

34. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a multinational retail corporation incorporated in the State of Delaware.

35. Along with retail stores and other business units, Walmart Inc. operates one of the largest pharmacy chains in the United States, consisting of more than 5,000 DEA-registered pharmacies located in Walmart and Sam's Club retail stores in the United States and its territories. As a pharmacy chain, Walmart Inc. dispenses controlled substances through its agents and employees.

36. Until 2018, Walmart Inc. also acted as a distributor of controlled substances for its pharmacies around the country. From 2000 to approximately May 2018, Walmart Inc. operated at least six distribution centers that distributed controlled substances to its pharmacies in the United States. Collectively, Walmart self-distributed to its pharmacies tens of millions of shipments of controlled substances.

37. The DEA registrant for those distribution centers was Defendant Wal-Mart Stores East, LP. Wal-Mart Stores East, LP, is also incorporated in Delaware.

38. At all times relevant to this action, Walmart Inc. was responsible for the compliance of the pharmacies and the distribution centers with all provisions of the CSA and the regulations promulgated under the CSA.

39. For ease of reference, Defendants Walmart Inc. and Wal-Mart Stores East, LP, are generally referred to herein as "Walmart" except where identification of the particular entity is significant. In addition, where it is useful to identify the business segment or refer to a brand (such as "Walmart-branded stores" or "Sam's Club-branded stores"), the distinction between those business segments or brands is drawn.

JURISDICTION AND VENUE

40. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1345, and 1355(a), and 21 U.S.C. §§ 842(c)(1) and 843(f)(2).

41. This Court has personal jurisdiction over both Defendants because both are incorporated in Delaware.

42. Venue is proper in this district under 28 U.S.C. § 1395(a) and 21 U.S.C. § 843(f) because both Defendants can be found and reside in this district.

I. WALMART'S CSA OBLIGATIONS AS A PHARMACY AND A DISTRIBUTOR.

A. Controlled substances generally.

43. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for abuse. Controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use to treat patients, their abuse potential, and the likelihood they will cause dependence if abused. A drug becomes a "controlled substance" when it is added to one of these schedules.

44. Schedule I drugs are those deemed not to have an accepted medical use. The remaining schedules—Schedules II through V—are relevant to this case. The drugs in these schedules have legitimate medical purposes and, in the case of Schedules II through IV, require a prescription. *See* 21 U.S.C. § 829.

45. Schedule II lists controlled substances that have "a high potential for abuse" and that, if abused, "may lead to severe psychological or physical dependence" but that nonetheless have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *See* 21 U.S.C. § 812(b)(2). Schedule II includes opioid-

based painkillers, such as oxycodone, hydrocodone, and methadone, and stimulants, such as amphetamine. *See* 21 C.F.R. § 1308.12.

46. Schedule III lists controlled substances that have "a potential for abuse less than the drugs or other substances in schedules I and II" and that, if abused, "may lead to moderate or low physical dependence or high psychological dependence" but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(3). Schedule III includes buprenorphine, a medication approved to treat opioid use disorder. *See* 21 C.F.R. § 1308.13.

47. Schedule IV lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule III" and that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III" but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(4). Schedule IV includes alprazolam (commonly sold under the brand name Xanax), diazepam (commonly sold under the brand name Valium), and lorazepam (commonly sold under the brand name Ativan). *See* 21 C.F.R. § 1308.14. Each of these three drugs belongs to a class of medications called benzodiazepines, which act on the brain and nerves to produce a calming effect. Schedule IV also includes carisoprodol, a muscle relaxant that is often sold under the brand name Soma, and zolpidem, an insomnia medication that is often sold under the brand name Ambien. As explained later, benzodiazepines, carisoprodol, and zolpidem are components of dangerous drug "cocktails" sought by individuals known to abuse or misuse prescription drugs.

48. Schedule V lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule IV" and that, if abused, "may lead to limited

physical dependence or psychological dependence relative to the drugs or other substances in schedule IV" but that nonetheless have "a currently accepted medical use in treatment in the United States." *See* 21 U.S.C. § 812(b)(5). Schedule V includes certain dosages of promethazine-codeine. *See* 21 C.F.R. § 1308.15.

B. The CSA creates a closed system for regulating controlled substances.

49. Through the CSA, Congress sought to prevent diversion of controlled substances. To accomplish this goal, the CSA created a "closed" system for regulating and monitoring controlled substances, under which it is unlawful to distribute, dispense, or possess any controlled substance except in a manner authorized by law. The CSA and its implementing regulations govern every step in the handling of certain drugs, from their production in a manufacturing facility to their distribution from a warehouse, and from their prescription by a medical practitioner to their dispensing by a pharmacy.

50. The system is "closed" in that each part of the supply chain—including manufacturers, distributors, prescribers, and pharmacies—must register with DEA. *See* 21 U.S.C. §§ 822(a)(2) and 823(f). Such "registrants" may manufacture, distribute, prescribe, or dispense controlled substances only to the extent authorized by their registration and the law. *See* 21 U.S.C. §§ 822(a)–(b), 823(f). All registrants, including pharmacies, "shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a).

C. A pharmacy must comply with certain legal requirements before it fills a controlled-substance prescription.

51. Ordinarily, the last step in the closed distribution system is the pharmacy that, after being presented with a prescription, dispenses a controlled substance to the end user.

52. Walmart operated pharmacies that "dispensed" controlled substances.

"Dispensing" generally means delivering a controlled substance to an end user pursuant to a physician's prescription. *See* 21 U.S.C. § 802(10); 21 C.F.R. §§ 1300.01, 1306.03(a).

53. Pharmacies that wish to dispense controlled substances are required under the CSA to register with the Attorney General. *See* 21 U.S.C. § 823(f). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01. A pharmacy's DEA registration is contingent upon the registrant's compliance with federal laws relating to controlled substances. 21 U.S.C. § 823(f).

54. Pharmacists who dispense controlled substances as an "agent or employee" of a pharmacy registered with DEA need not register individually with DEA. *See* 21 U.S.C. §§ 822(c)(1), 823(f).

55. The CSA permits the dispensing of controlled substances by a registered pharmacy. However, § 829 requires pharmacies to "dispense" controlled substances based only on a prescription issued by a practitioner. *See* 21 U.S.C. § 829(a) ("no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner"), § 829(b) (requiring a prescription for dispensing controlled substances in Schedule III or IV).

56. In Part 1306 of 21 C.F.R., the Attorney General adopted rules that "specifically" govern the scope of conduct allowed by 21 U.S.C. § 829. *See* 21 C.F.R. § 1306.01 ("Rules governing the . . . filling . . . of prescriptions pursuant to . . . 21 U.S.C. § 829 . . . are set forth generally in that section and specifically by the sections in this part."); *see generally* 21 C.F.R. §§ 1306.01–27. Part 1306 includes rules applicable to both the registered pharmacy and individual pharmacists.

1. Controlled substances may be dispensed only pursuant to prescriptions that are issued by practitioners in the usual course of professional practice and for legitimate medical purposes.

57. Controlled substances may be dispensed only pursuant to prescriptions that are "effective," meaning valid. 21 C.F.R. § 1306.04(a).

58. To be valid or effective, a prescription for a controlled substance must be issued "by an individual practitioner acting in the usual course of his professional practice" and "for a legitimate medical purpose." *See* § 1306.04(a).

59. While § 1306.04(a) imposes a responsibility on prescribers to issue valid prescriptions, it also imposes a "corresponding responsibility" on the pharmacist who fills a prescription to independently determine that the prescription was issued in the usual course of professional practice and for a legitimate medical purpose. *See* § 1306.04(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.").

60. In addition to imposing these obligations on the prescriber and the pharmacist, § 1306.04(a) imposes an obligation on the "person" responsible for the dispensing of the controlled substance. Specifically, the regulation provides that any "person knowingly filling" an invalid prescription is subject to penalties. Under the CSA, "person" includes both individuals and corporations. *See* 21 C.F.R. §§ 1300.01, 1306.02.

61. When a corporation is the DEA registrant, that corporation is responsible for its pharmacies' compliance with the CSA. 21 U.S.C. § 822(b), § 823(f). If one of its pharmacies dispenses a controlled substance based on an invalid prescription with the knowledge of any corporate personnel acting within the scope of their employment, the corporation is the "person"

liable under § 1306.04(a). If a pharmacist dispenses a controlled substance based on a prescription the pharmacist knows is invalid, the pharmacist is the "person" who violates § 1306.04(a). And when a corporation employs pharmacists to act as its agents in dispensing controlled substances, that corporation also can be liable for any violations of § 1306.04(a) committed by any pharmacist who knowingly filled invalid prescriptions while acting within the scope of their employment.

2. The pharmacist, in dispensing, also must adhere to professional pharmacist practice standards, which require identifying and resolving any red flags.

62. In addition to prohibiting a pharmacist from knowingly dispensing an invalid prescription, the CSA and its regulations also require a pharmacist in "dispensing" controlled substances to follow the "usual course of professional practice." 21 U.S.C. § 829 authorizes a "practitioner" (such as a pharmacy) to "dispense" a controlled substance pursuant to a prescription. *See* 21 U.S.C. § 829(a) ("Except when *dispensed* directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II . . . may be *dispensed* without the written prescription of a practitioner . . . .") (emphasis added); § 829(b) ("Except when *dispensed* directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV . . . may be *dispensed* without a written or oral prescription . . . .") (emphasis added).

63. "Dispense" is a term of art defined by the CSA. Under that definition, only certain conduct is deemed "dispensing." Specifically, "dispensing" refers to conduct by a "practitioner" (such as a pharmacy) that delivers a controlled substance to a user pursuant to a prescriber's order. *See* 21 U.S.C. § 802(10) ("The term 'dispense' means to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner . . . . The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate

user . . . .").

64. "Practitioner" is also a term of art defined by the CSA. Doctors and pharmacies are deemed "practitioners" only to the extent they act in the "course of professional practice." 21 U.S.C. § 802(21) ("The term 'practitioner' means a physician, . . . pharmacy, . . . or other person licensed, registered, or otherwise permitted, . . . to . . . dispense, . . . a controlled substance in the course of professional practice . . . ."); *see Gonzales v. Oregon*, 546 U.S. 243, 244 (2006) (citing the definition of "practitioner" in § 802(21) and explaining that physicians are considered "practitioners" only "if they dispense controlled substances 'in the course of professional practice'").

65. These definitions limit the scope of the dispensing conduct authorized in § 829. Practitioners, such as pharmacies, may dispense controlled substances pursuant to prescriptions, but only if their conduct follows the "course of professional practice."

66. The CSA's regulations adopt this statutory limitation, restricting dispensing to the usual "course of professional practice." In particular, § 1306.06 provides that "a prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06.

67. Accordingly, for a pharmacist to comply with the limited dispensing authorization provided in 21 U.S.C. § 829, the pharmacist must dispense the controlled substances in the usual "course of professional practice." A pharmacist whose conduct in filling controlled-substance prescriptions falls outside the usual course of professional practice has not complied with § 829.

68. The obligation to follow the usual course of professional practice when dispensing controlled substances focuses on the pharmacist's conduct during the dispensing process. This obligation thus differs from the obligation imposed by 21 C.F.R. § 1306.04(a),

which focuses on the prescription's validity, defining when prescriptions are valid and the consequences that may be imposed based on the prescription's invalidity. If a person fills an invalid prescription without knowledge that the prescription was invalid, then the person has not violated § 1306.04(a). But pharmacists engaged in dispensing pursuant to 21 U.S.C. § 829—like any "practitioner" authorized to handle controlled substances—must still comply with their basic professional obligations in the dispensing process, regardless of whether the prescription is valid.

69. Pharmacists are trained professionals who must be licensed by the states in which they practice. A basic licensing requirement common across states is a Doctor of Pharmacy ("Pharm.D.") degree.

70. In the field of pharmacy, it is recognized that pharmacists have essential responsibilities when presented with prescriptions for controlled substances. A pharmacist evaluating the validity of a controlled-substance prescription cannot rely exclusively on the fact that it was issued by a medical practitioner. Rather, to assess a prescription's validity, a pharmacist must act as an independent professional and must consider any signs that a prescription may be invalid.

71. Indeed, one of the key professional responsibilities of a pharmacist, when presented with a prescription for controlled substances, is to identify the presence of red flags of diversion. This responsibility has been recognized as an important safeguard against the diversion of controlled substances. For example, in 2014, the National Association of Boards of Pharmacy released a video called "Red Flags," which observed that "by recognizing red flags to help establish the validity of a prescription, the pharmacist becomes the last line of defense in preventing misuse." The video states that "problem prescriptions can often be identified by using common sense, practicing good pharmacy, and looking for red flags that suggest the

prescription may not be legitimate."

72. Red flags indicative of invalidity may arise based on the prescriber who issued the prescription (e.g., where a prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals), the prescription itself (e.g., where the combination of drugs prescribed is frequently sought by individuals known to abuse or misuse prescription drugs), or the individual presenting the prescription (e.g., where a patient repeatedly seeks early refills).

73. A second basic professional obligation of pharmacists presented with controlled-substance prescriptions is to resolve each red flag they identify. Depending on the circumstances, the pharmacist might need to verify information, contact the prescriber, check a state prescription drug monitoring program website to determine what other prescriptions the patient is receiving, or take some combination of these or other steps.

74. Third, if a pharmacist identifies and resolves red flags, the pharmacist has an additional professional responsibility to document that resolution. Documentation serves multiple purposes. It ensures that the pharmacist did in fact adequately resolve the red flag. In addition, it ensures that the information about the red flag and its resolution is available to the pharmacist and others for future reference. Because documentation is part of the usual course of professional pharmacy practice, the absence of documentation can indicate that the pharmacist did not successfully resolve the red flag. Thus, pharmacists presented with a controlled-substance prescription bearing a red flag must investigate and either (a) resolve the red flag before dispensing *and* document the resolution, or (b) refuse to fill the prescription.

75. These basic professional obligations apply when a pharmacist fills any controlled-substance prescription showing a red flag, regardless of whether the prescription is valid or not.

Even if a prescription turns out to be valid, a failure to take these basic steps violates the usual course of professional practice for pharmacists.

76. Because these three obligations—to identify red flags, to resolve them before filling the prescription, and to document any resolution of red flags—are recognized procedural responsibilities of pharmacists in the professional practice of pharmacy, a pharmacist who fails to fulfill them when dispensing controlled substances does not adhere to the usual course of his or her professional pharmacy practice as required by 21 U.S.C. § 829 and 21 C.F.R. § 1306.06.

3. Violations of these dispensing rules subject the pharmacy to civil penalties and other appropriate relief.

77. The CSA makes it unlawful "for any *person* . . . subject to the requirements of part C [21 U.S.C. §§ 821–32] to distribute or dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1) (emphasis added). A person dispensing controlled substances not in compliance with § 1306.04(a) or § 1306.06 violates 21 U.S.C. § 829 and thus 21 U.S.C. § 842(a)(1). *See* 21 C.F.R. § 1306.01 ("Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.").

78. Under the CSA, a person is liable for a civil penalty for each violation of 21 U.S.C. § 842(a)(1).

79. The CSA provides that a person who violates 21 U.S.C. § 842(a)(1) shall, with respect to any such violation, be subject to a civil penalty not to exceed $25,000 for each violation on or before November 2, 2015, and not to exceed $72,683 for each violation after November 2, 2015. *See* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.

80. The CSA also authorizes the Attorney General to seek "appropriate declaratory or injunctive relief relating to violations of … section 842 … of this title," 21 U.S.C. § 843(f)(1),

and authorizes the Court to issue an order "tailored to restrain violations of … section 842 of this title." 21 U.S.C. § 843(f)(3).

D. Distributors must comply with certain legal requirements when they receive controlled-substance orders from pharmacies.

81. The CSA defines a "distributor" as a person or an entity that delivers (other than by administering or dispensing) a controlled substance. The CSA defines "delivery" as the "actual, constructive, or attempted transfer of a controlled substance." *See* 21 U.S.C. § 802(8), (11).

82. Walmart—as noted above—served as its own controlled-substance distributor until 2018, and it operated several dedicated distribution facilities during the Distribution Violations Period.

83. Distributors of controlled substances are required by the CSA to register with DEA and to maintain effective controls against the diversion of controlled substances for illegitimate uses. *See* 21 U.S.C. § 823(b)(1) (requiring the Attorney General, in registering a distributor, to consider whether the distributor has shown "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels"). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

1. Distributors must report suspicious orders.

84. Under the CSA, it is unlawful for a distributor to distribute a controlled substance "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a) ("Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally (1) to . . . distribute . . . a controlled substance; . . . .").

85. The CSA provides the Attorney General broad authority to "promulgate and

enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b); *see also* 21 U.S.C. § 821. The Attorney General has issued numerous regulations under the referenced subchapter —Subchapter I —establishing an extensive regulatory regime. *See* 21 C.F.R. §§ 1300.01-1321.01.

86. In particular, the Attorney General, by regulation, has long required distributors to design and operate a system to detect suspicious orders of controlled substances and to report those orders to DEA. *See* 21 C.F.R. § 1301.74(b). This provision reads, in full, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

2. Failure to report suspicious orders subjects the distributor to civil penalties.

87. If a distributor fails to report a suspicious order, it violates the law. Under 21 U.S.C. § 842(a)(5), it is unlawful for any person, including a distributor, "to refuse or negligently fail to make, keep, or furnish any record, report, notification, … or information required under" Subchapter I.

88. A distributor is liable for a civil penalty for each violation of 21 U.S.C. § 842(a)(5).

89. The CSA provides that a person who violates 21 U.S.C. § 842(a)(5) shall, with respect to any such violation, be subject to a civil penalty not to exceed $10,000 for each violation on or before November 2, 2015, and not to exceed $16,864 for each violation after November 2, 2015. *See* 21 U.S.C. § 842(c)(1)(A), (B); 28 C.F.R. § 85.5.

II. WALMART, AS A PHARMACY, VIOLATED THE CSA.

90. Walmart filled invalid prescriptions in violation of § 1306.04(a) through both the knowing actions of certain compliance team members and the knowing actions of certain pharmacists. Walmart also violated § 1306.06 when its pharmacists failed to identify, resolve, and document the resolution of red flags when filling prescriptions.

A. Walmart Pharmacies: Factual Background

91. Walmart's Health and Wellness Division ran the company's pharmacies, optical and hearing services, and over-the-counter drug sales. The Health and Wellness Compliance team ("compliance team"), within the Health and Wellness Division, operated out of Walmart's headquarters in Bentonville, Arkansas (called the "home office").

92. The compliance team was overseen by a vice president. At least four individuals, J.L., D.B., G.H., and D.S., served in that role at different times during the Dispensing Violations Period. The vice president was supported by supervisory staff consisting of senior directors, directors, and senior managers. The individuals occupying those roles included G.C., R.I., M.J., T.K., D.M., B.N., C.R., and S.T. The compliance team was entrusted with ensuring Walmart's compliance with various laws, including the CSA. Among other things, they established policies and procedures related to pharmacies' compliance with the CSA. Compliance team members in the home office oversaw managers in the field, including market directors and regional directors. Those field directors had responsibility for the pharmacies within certain geographic regions. Each pharmacy was supervised by a pharmacy manager who oversaw the pharmacists and pharmacy technicians.

93. In June 2014, Walmart employees B.N., S.T., and C.R. were promoted from senior managers to directors on the compliance team. As senior managers and later as directors, they were "responsible for advancing [Walmart's] programs and policies related to controlled

substances." In those roles, they contributed to defining the policies that governed pharmacists' controlled-substance dispensing, had the authority to control pharmacists' dispensing, gave direction to pharmacy employees in response to specific questions about dispensing, and in some instances declined to exercise their authority to provide specific direction.

94. In October 2014, M.J. became the Director of Controlled Substances. As the director, M.J. had responsibility for, among other things, the refusal-to-fill process and controlled-substance risk assessment projects, and she also gave, and sometimes chose not to give, direction to pharmacy employees in response to specific questions about dispensing controlled substances. Other members continued to have responsibility over matters related to controlled substances, including B.N., S.T., C.R., and their supervisors.

1. Walmart was put specifically on notice of its preexisting regulatory obligations through a 2011 settlement with DEA.

95. In March 2011, Walmart entered into a nationwide memorandum of agreement ("MOA") with DEA to resolve an administrative action arising from a California Walmart pharmacy's alleged filling of controlled-substance prescriptions that were not issued for a legitimate medical purpose or by a prescriber acting within the usual course of professional practice.

96. The MOA was in effect from March 2011 through March 2015. Walmart committed to, among other things, "maintain a compliance program, updated as necessary, designed to detect and prevent diversion of controlled substances as required by the Controlled Substances Act."

97. The MOA required Walmart's compliance program to include procedures to identify the common signs associated with the diversion of controlled substances, including but not limited to doctor shopping, requests for early refills, altered or forged prescriptions,

prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice.

98. In the MOA, Walmart also agreed that if one of its pharmacists concluded that a prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, was forged, or had been altered and refused to fill that prescription, Walmart would notify the local DEA field office within seven business days of the refusal to fill. The compliance team was responsible for the refusal-to-fill process.

2. Walmart's compliance team had the responsibility and authority to supervise pharmacists' dispensing decisions.

99. Walmart's compliance team had responsibilities related to the company's compliance with the CSA, including establishing and implementing policies to ensure that Walmart pharmacists filled only valid prescriptions and that they filled prescriptions in a manner consistent with professional pharmacy standards.

100. The highest levels of management at Walmart knew their policies directly affected what its pharmacists did and did not dispense and how they arrived at those dispensing decisions. For instance, P.B., the Senior Vice President of Operations for the Health and Wellness Division, said in an August 2013 leadership message, "Walmart and Sam's Club have in place a number of robust policies and procedures to help you identify those instances in which it may not be proper to fill a controlled substance prescription."

101. For example, one of the policies designed to help pharmacists identify those prescriptions that should not be filled was a requirement that pharmacists check their state's prescription monitoring database, which contained dispensing data, before filling prescriptions for oxycodone immediate-release 30mg. This requirement was implemented in July 2012.

102. Walmart's management also knew that they directly affected pharmacists' dispensing decisions through not only their policies, but also the tools they chose to make available. In the same leadership message, P.B. urged pharmacists to "[u]se the tools we have made available to you to assist you in exercising your judgment and to fill prescriptions responsibly."

103. Because they were responsible to ensure that Walmart satisfied its legal obligations, the compliance team also had the ultimate authority to instruct Walmart's pharmacists to refuse to fill specific prescriptions. In September 2014, for example, B.N. directed a pharmacist not to fill a hydrocodone prescription that was affected by the rescheduling of the drug from Schedule III to II. After being thanked for his help, B.N. wrote, "No worries, that's why we are here, to say NO!! :-)."

104. The compliance team thus had the authority to stop Walmart pharmacists from filling invalid prescriptions and to ensure that they made dispensing decisions consistent with professional practice standards. As detailed below, however, the team chose, for years, not to exercise that authority to ensure that Walmart was in compliance with its legal obligations.

3. Walmart's policy, titled "POM 1311," established by the compliance team, instructed pharmacists to evaluate the patient-practitioner relationship and document refusals to fill, but it prohibited pharmacists from blanket refusing to fill for a prescriber.

105. Walmart's pharmacy policies, collected in its Pharmacy Operations Manual ("POM"), acknowledged in POM 1311 the duties imposed by the CSA. From at least 2009 until 2015, POM 1311 was titled "Proper Practitioner-Patient Relationship." POM 1311 included an "overview" section, which stated that "[u]nder federal rules and the laws of many states, in order for a prescription to be valid, there must be a proper prescriber-patient relationship." The POM then provided pharmacists with a non-exhaustive list of factors indicating when a proper

prescriber-patient relationship may not exist. It stated that if a pharmacist has a reasonable suspicion that a proper prescriber-patient relationship may not exist, the pharmacist must verify the relationship. The verification process, according to POM 1311, should include contacting the prescriber and asking certain questions. No later than the March 2011 version of POM 1311, the policy acknowledged that pharmacists should not blindly accept a prescriber's assurances: "Simply because the prescriber verifies that he or she has seen the patient does not mean that an 'appropriate' patient prescriber relationship exists; if other signs of an inappropriate relationship are present, the pharmacist can still exercise his or her judgment and not fill the prescription at issue." POM 1311 instructed pharmacists not to dispense prescriptions if they did not believe that a valid prescriber-patient relationship existed. If, however, after contacting the prescriber, the pharmacist reasonably believed there was a valid prescriber-patient relationship, POM 1311 instructed the pharmacist to "make a notation on the prescription" stating the pharmacist's name, prescriber's name, the date of the conversation with the prescriber, and the notation, "'proper relationship verified'."

106. POM 1311, however, also provided that "[b]lanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or for a valid medical reason before refusing to fill." In other words, the compliance team prohibited pharmacists from making their own determination to not fill any prescriptions from a particular prescriber based on the pharmacists' concerns with that prescriber's practice.

107. As early as 2009, pharmacists were required to notify the home office whenever they refused to fill a prescription. POM 1311 (2009) instructed pharmacists to "notify Professional Services who will assist in determining whether to notify the corresponding

examining board for the prescriber or other appropriate authorities." After the 2011 MOA, pharmacists notified the compliance team by completing a Walmart-created refusal-to-fill webform. The form included fields for the pharmacist to input information about the prescription, the identity of the patient and prescriber, the prescriber's DEA registration number, and the date of the refusal. Initially, the refusal-to-fill form also included two fields for the pharmacist to explain, in their own words, why they refused to fill the prescription.

108. The completed refusal-to-fill forms were transmitted to employees of the compliance team. From 2011 until 2015, B.N. was responsible for monitoring the electronic mailbox used to receive these forms. He forwarded some of the information contained in the forms to DEA, as required by the MOA. He did not, however, forward the explanations from pharmacists about why they had refused to fill prescriptions. Those explanations often included alarming comments about prescribers or patients. Instead, the compliance team designated the reason for each refusal as either "other than legitimate medical purpose" or "forged rx." When M.J. became Director of Controlled Substances in October 2014, she assumed responsibility for the refusal-to-fill process. But B.N. retained responsibility for sending information about refusals to DEA through the expiration of the MOA in March 2015.

4. In response to pharmacist questions, Walmart's compliance team offered boilerplate responses that incorrectly told pharmacists that refusing to fill invalid prescriptions was optional and that states prohibited blanket refusals to fill.

109. Pharmacists and their field supervisors regularly asked the compliance team for guidance when the POM did not answer their questions. The compliance team, however, often simply relied on a boilerplate reply—referred to by senior director D.M. as the "POM [1311] response"—that failed to address the specifics of the pharmacists' concerns.

110. The boilerplate POM 1311 response provided, "Pharmacists are granted the

ability to exercise their professional judgment and choose to refuse to fill any prescription if they feel the prescription was written for other than a legitimate medical purpose . . . . Even after the Pharmacist established that there is a Dr/Patient relationship, the Pharmacist is still allowed to refuse to fill a prescription on an individual prescription basis, no blanket refusals are allowed by the Boards of Pharmacy." This categorical statement, repeated and reinforced countless times by the compliance team, was inaccurate in two respects. First, it communicated to pharmacists that refusing to fill invalid prescriptions was optional; it said that if the pharmacist believed a prescription was invalid, the pharmacist had "the ability" to "choose to refuse to fill" the prescription. In fact, the law required pharmacists to refuse to fill invalid prescriptions. Second, the compliance team's assertion that state law prohibited blanket refusals was based on merely oral conversations with a limited number of state boards of pharmacy, and not on a statute or regulation of any state.

5. Walmart's compliance team offered controlled-substance training but failed to equip pharmacists with refusal-to-fill information.

111. In August 2013, Walmart acknowledged that additional controls were needed to meet its legal obligation to prevent diversion. It distributed a leadership message and instituted new training for the purpose of "reminding [Walmart's] pharmacists of their responsibility and duty in using their professional judgment in the dispensing of controlled substances." The leadership message began by recognizing events that appeared to be the impetus for Walmart's action: "headlines regarding recent DEA enforcement actions against several retail pharmacies" and "recently enacted strict policies for [other companies'] pharmacists to follow when dispensing controlled substances."

112. S.H. and G.C. "owned" this project, but other members of the compliance team knew of the project, and the nationwide distribution of the leadership message and new training

to all pharmacists reflected the intent for all compliance team members and pharmacists to know and abide by the guidelines described in the training.

113. The August 2013 training acknowledged that the obligation to evaluate prescriptions to ensure their validity was a legal obligation. The training included a video message from P.B. and J.T.M., Senior Vice President of Health and Wellness for Sam's Club, that reminded pharmacists that their "corresponding responsibility" to evaluate prescriptions was based on 21 C.F.R. § 1306.04 and that this regulation "obligated [pharmacists] to watch for the warning signs of dependency and abuse."

114. Walmart's training video cautioned pharmacists that "[j]ust because a licensed prescriber writes and confirms a controlled substance prescription does not mean that it was issued for a legitimate medical purpose."

115. The new training included a "red flags" document, which grouped warning signs of invalid prescriptions into three categories: prescriber red flags, prescription red flags, and patient red flags. The red flags document described prescriber red flags as "[t]hose concerns arising from the specific prescriber and how he or she tends to prescribe in the course of practice." To evaluate a prescription, the document advised pharmacists to ask themselves whether there was "anything about this specific prescriber that is of concern?"

116. "[M]onitoring for prescribers who may contribute to the problem of drug abuse and addiction" was part of exercising corresponding responsibility, according to the August 2013 training. But individual pharmacists did not always know about the egregious prescription-writing patterns of certain prescribers because they were unaware of the experiences of other Walmart pharmacists across the country. Thus, they were often not in a position to adequately monitor prescribers. The Health and Wellness Division acknowledged this reality when it

explained that the information contained in refusal-to-fill forms "will help the Home Office help all of you identify trends observed throughout the nation that could be relevant to your exercise of professional judgment."

117. A few months after the training, in October 2013, the compliance team set a goal of analyzing the refusal-to-fill information and establishing a way to distribute the information internally. But, for years, the goal was not met because it simply was not a priority. *See infra* ¶¶ 177-179, 198-206.

6. Walmart's compliance team eventually revised POM 1311 and updated the refusal-to-fill process, but still did not adequately equip pharmacists with refusal-to-fill information.

118. In October 2014, the compliance team reorganized its controlled-substances projects and subsumed them into a single project called "controlled substances risk mitigation." One of the projects was to update the POM.

119. Walmart issued its revised POM 1311 in July 2015 and renamed it "Proper Prescriber-Patient Relationship/Corresponding Responsibility." The "overview" section was changed to acknowledge that a valid prescription must not only be based on a proper prescriber-patient relationship, but also be for a legitimate medical purpose: "Under federal law, pharmacists may only dispense a controlled substance prescription issued for a legitimate medical purpose and based on a proper prescriber – patient relationship." The revised POM 1311 quoted directly from 21 C.F.R. § 1306.04(a) and explained that this regulation was the basis for nearly all criminal actions taken by DEA against pharmacies and pharmacists.

120. POM 1311 (2015) instructed pharmacists to review each prescription carefully to determine whether it was written for a legitimate medical purpose and listed red flags that might indicate that a prescription was not issued for such a purpose. POM 1311 listed the following

prescriber red flags, patient red flags, and prescription red flags:

Prescriber Red Flags:

- Prescription is written by a prescriber outside of the pharmacy's trade area.
- Prescriber routinely prescribes a large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances.
- Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.
- Prescriber routinely writes for large doses of controlled substances.
- Prescriber provides the same diagnosis for the majority of individuals.
- Prescriber engages in the unauthorized practice of medicine, including writing prescriptions outside of scope of practice and/or not having a proper relationship with the patient.

Patient Red Flags:

- Individual insists on paying cash, or insists on paying cash for controlled substances even though insurance is on file.
- Evidence of "doctor shopping" exists.
- Evidence of "pharmacy shopping" exists.
- Individual resides outside of the trade area of [the] pharmacy.
- The individual's statements and conduct or behavior suggest abuse of controlled substances.
- Individual asks for certain drugs prone to abuse by color, trade name or markings and/or uses "street names."
- Individual routinely attempts to obtain an early refill on controlled substances.

- Individuals have suspicious relationships with each other. For example: multiple patients filling prescriptions from one address; prescriptions being presented by someone other than the patient; groups of patients arriving all with prescriptions for the same medication from the same doctor.

Prescription Red Flags:

- Prescriptions presented represent a "cocktail" of commonly abused drugs or are presented in a combination that can cause medical complications.
- Prescription presented is for an unusually large quantity or high starting dose.
- Prescription appears to be altered or duplicated.
- Prescription has an electronically generated or rubber-stamped signature.

121. POM 1311 (2015) stated that, before a pharmacist fills a controlled-substance prescription with any of these red flags, the red flags "should be evaluated, resolved, and documented." It further instructed pharmacists to "[d]ocument the results of the red flag evaluation in the Rx Notes field of Connexus." Connexus was the system that pharmacists used to input prescriptions. Additionally, the POM provided that if a pharmacist determined that a controlled-substance prescription should not be dispensed, "the pharmacist **must** immediately complete the Refusal to Fill form." (Emphasis in original.) The POM explained that this form "provides important details of the transaction so that Practice Compliance may take appropriate follow up action."

122. POM 1311 (2015) no longer contained an explicit ban on blanket refusals to fill, but it still stated that "[a] pharmacist must make an individual assessment of each prescription to determine if the prescription is written for a legitimate medical purpose."

123. In July 2015, Walmart also announced that it had transferred the refusal-to-fill

process from Walmart's standalone webform to the company's online "Archer" platform, which was used for various pharmacy compliance tasks. The Archer platform allowed pharmacists to search and view refusal-to-fill information, but, as discussed below, *see infra* ¶¶ 198-206, Archer's search functionality was not readily accessible and not widely known or used.

7. Following DEA's search of a Walmart pharmacy, the compliance team again revised POM 1311, explicitly permitted blanket refusals to fill, and instituted corporate blocks of prescribers and other anti-diversion measures.

124. On December 7, 2016, pursuant to a search warrant, DEA searched a Walmart pharmacy in Texas, putting Walmart on notice that the Department of Justice was investigating the company for its dispensing of controlled substances.

125. Six days later, J.L., the compliance team's vice president, reviewed the boilerplate POM 1311 response that the directors, B.N., C.R., and S.T., had been sending to pharmacy employees in the field in response to questions related to their corresponding responsibility. The compliance team later discontinued the boilerplate POM 1311 response.

126. About one month after the search, J.L. circulated to the senior directors and directors a list of "accelerated controlled substance efforts." Those efforts included, among others, the following:

- Enhance [refusal to fill] reporting, analysis, and [point of sale] utilization
- Rollout of blanket refusal program to the field
- [Home office] level prescriber blocking program

127. The compliance team announced the prescriber-blocking program to the field on January 6, 2017, in its "Leadership Weekly" bulletin distributed by Walmart's Health and Wellness Division. The bulletin explained that "[f]eedback via refusal to fill forms along with expanded visibility to prescriber patterns has led to specific dispensing insights," and after

review, "these additional data may lead Wal-Mart and Sam's Club to place a block in Connexus on controlled substance prescriptions for these prescribers."

128. Ten days after the announcement, Walmart instituted its first corporate block, prohibiting all Walmart pharmacists from filling controlled-substance prescriptions written by prescriber F.B. *See infra* ¶¶ 245-254. Over time, Walmart identified additional prescribers of concern through what it called its "prescriber review program," which began in or about February 2017, and by December 31, 2018, the company had blocked 360 prescribers.

129. However, at the same time the compliance team was pursuing "accelerated controlled substance efforts," it also took steps to reduce the amount of information that it both provided and received in writing.

130. For example, in February 2017, C.R. asked fellow director M.J. for feedback on her proposed response to a question from the field about a prescriber who was under investigation. She sent to M.J. the response she had shared with employees "[i]n the past," which included language from the boilerplate POM 1311 response, but C.R. noted that "now I know we should refrain from sending anything in writing."

131. Also in February 2017, the compliance team removed the comments field in Archer's refusal-to-fill form and added a drop-down menu of pre-populated reasons for the refusal to fill. Thus, when completing refusal-to-fill forms, pharmacists no longer were able to explain in their own words why they refused to fill prescriptions. If a pharmacist wanted to provide details about a refusal to fill, the pharmacist had to ask to be contacted by someone in the compliance team. Pharmacists who wanted to provide additional details received an email instructing them, "**Do not reply to this email with the additional details regarding the Refusal to Fill.** Only phone calls or phone messages are acceptable forms of communication."

(Emphasis in original.)

132. The compliance team also issued a new version of POM 1311 in February 2017 with "significant updates." POM 1311 (2017) informed pharmacists, for the first time, that they were allowed to impose blanket refusals to fill: "If, based on the pharmacist's professional judgment, a pharmacist identifies a pattern of red flags with a prescriber that are unresolvable, a pharmacist may refuse all controlled substance prescriptions from that prescriber ('Blanket Refusal') without evaluating every future controlled substance prescription presented from that prescriber." The POM then described the process a pharmacist should follow to impose a blanket refusal to fill, which included completing the blanket refusal form in Archer.

133. Initially, the blanket refusal form in Archer did not contain a comments field for the pharmacist to explain why they imposed a blanket refusal. A comments field was not added until February 2018. POM 1311 (2017) also required the pharmacist to share the blanket refusal decision with the pharmacist-in-charge and other pharmacists at the pharmacy but instructed pharmacists that "[t]his must occur through an oral communication."

134. POM 1311 (2017) added four red flags to the list of prescriber, prescription, and patient red flags, *see supra* ¶ 120:

- Prescriber red flag: Prescriber is under investigation or has been disciplined for inappropriate prescribing of controlled substances.
- Prescription red flag: The prescription is presented to the pharmacy by someone other than the ultimate user of the controlled substance or a member of his or her household.
- Prescription red flag: Prescriptions for drugs with opposite effects (e.g. stimulants and depressants).
- Prescription red flag: Prescription for drugs with similar effects (e.g. multiple long acting

or multiple short acting opioids).

135. The compliance team also added the following sentences to its discussion of evaluating red flags: "Professional judgment may include knowledge or information from other pharmacists or prior experience with the prescriber or patient. It may also include knowledge that another pharmacy is refusing to fill a prescriber's prescriptions."

136. In November 2018, Walmart began a pilot program to integrate refusal-to-fill data into Connexus. During the prescription input process, pharmacists would be notified of the total number of refusal-to-fill forms and blanket refusals submitted for the prescriber and could connect from Connexus to Archer to view the information. This functionality was scheduled to be available in all pharmacies by May 2019, making refusal-to-fill information accessible to pharmacists through Connexus for the first time. However, the refusal-to-fill information still had limited utility to pharmacists because it did not include the pharmacists' comments explaining in their own words their refusals.

137. Also in 2018, Walmart instituted additional anti-diversion initiatives. In approximately June 2018, Walmart implemented a program to restrict, subject to pharmacist discretion, initial opioid prescriptions for acute conditions to no more than a seven-day supply, with a maximum daily dosage of 50 morphine milligram equivalent ("MME"), which was a measure of the strength of the prescribed opioid. The company defined an acute condition as one that "usually occurs suddenly," "has a known cause," and "normally resolves as the body heals." The company also revised various POM provisions, instituted new training for its pharmacists, and provided access to a data analytics tool that helped assess risk from controlled substances. And over the following years, Walmart blocked thousands of doctors it identified as "questionable."

138. At no time, however, has Walmart provided its pharmacists with all the information that was known to the compliance team about pill-mill prescribers. For years, Walmart chose not to alert pharmacists to the existence of derogatory prescriber information known by the compliance team. By the time Walmart made the refusal-to-fill information available to pharmacists, the information was limited because the comments field had been removed and pharmacists were required to choose from a fixed list of options to explain their refusals. As a result, pharmacists continued to fill prescriptions without knowing information about certain prescribers' pill-mill practices.

8. Walmart pressured its pharmacists to fill prescriptions as quickly as possible, often with inadequate staffing.

139. The compliance team's decisions described above exacerbated an already challenging environment in which pharmacists made dispensing decisions. Walmart pharmacists work in a highly regulated profession, but they are also employees of one of the world's largest companies, which earns billions of dollars in profits annually. Retailers like Walmart operate pharmacies primarily to draw customers into their stores with the expectation that those customers will buy other, non-pharmacy goods. For example, in 2014, Walmart calculated that the average pharmacy customer spends 67 percent more than the average non-pharmacy customer. Later, Walmart observed in its fiscal year 2017 annual report that risks to its pharmacy business could "result in the loss of cross-store or -club selling opportunities and, in turn, adversely affect our overall net sales, other results of operations, cash flows and liquidity." In another example, Sam's Club at times offered drastic discounts on opioids that helped drive customer traffic to its stores.

140. Walmart employees repeatedly told pharmacists to fill prescriptions as quickly as possible, in an effort to keep pharmacy customers in the stores. For example, a December 17,

2014, email to certain pharmacists stated that "shorter wait times keep patients in store." Other emails urged that if prescriptions were not filled quickly, customers would shop elsewhere. And one Walmart manager told pharmacists to "[h]ustle to the customer, hustle from station to station" because filling prescriptions "is a battle of seconds."

141. Walmart's Weekly Key Metrics report, which was store-specific and distributed to that pharmacy's staff, measured prescription counts and changes, on-time fills, profits, and other business metrics. The only metric associated with patient safety was a measurement of how accurately prescriptions were input.

142. Walmart also adopted, as early as 2013, Pharmacy Facility Management Incentive Plans, which used the number of prescriptions filled by a pharmacy employee's store as a factor in determining whether the pharmacy employee was entitled to monetary incentive awards.

143. The pressures created by these policies added to the pressures from understaffing. Walmart conducted and received the results of an Agency for Healthcare Research and Quality survey of many of its pharmacy employees in June 2012, July 2014, and October 2014. In response, a substantial number of pharmacy employees reported that their pharmacy lacked sufficient staff to handle the workload. In June 2012, only 59 percent of the employees reported having sufficient staff to handle the workload. By October 2014, only 43 percent reported having sufficient staff. Not surprisingly, a large percentage of staff thus felt rushed with processing prescriptions. In the October 2014 survey, more than half—54 percent—reported that they felt rushed.

144. Many pharmacy employees responded to the surveys with specific written pleas for more staffing and time to carry out their duties in filling prescriptions. They commented that inadequate staffing compromised patient safety and that pressure from managers to fill

prescriptions quickly caused pharmacists to take shortcuts. As just a few of the many examples from the October 2014 survey, pharmacy employees reported the following:

- "[Staffing] is too low for a pharmacy and is dangerous for patients if the staff always feels overwhelmed or rushed while working on patients['] prescriptions."
- "Inadequate staffing is a big safety issue as it results in each person juggling more than they should, and opens up the potential for mistakes to occur as a result."
- "I have worked for Walmart for over 10 years and generally feel that pharmacist staffing is generally inadequate to provide an environment for a pharmacist to perform tasks in a manner that is truly safe."
- "[B]ecause of the constant harassment from our market manager about us not getting [prescriptions] done in 20 min, we often take shortcuts in filling and counseling rx's that could lead to patient safety issues."
- "[I]f patient safety is the concern, numbers should not matter more than the patients['] health. [M]arket manager and store manager are to[o] preoccupied with sales and numbers[. T]hey prefer us to rush and get rx out…."
- "Us being criti[c]ized b[y] our Health and Wellness Director about not getting prescriptions out in 20 minutes causes the pharmacy to take short cuts and affects patient safety."

(Emphases omitted.)

B. Walmart filled invalid prescriptions in violation of 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a) through the knowing actions of certain compliance team members and pharmacists.

1. Walmart unlawfully filled thousands of prescriptions that one or more members of its compliance team knew were invalid.

145. All dispensers of controlled substances are subject to the limits established in

§ 1306.04(a). The CSA makes no distinction between individual and corporate dispensers. *See supra* ¶ 60. Walmart, as a corporation, sought authority to dispense controlled substances, held more than 5,000 registrations permitting it to do so, and was responsible for any violations of the duty to fill only valid prescriptions.

146. Walmart violated that duty, filling thousands of invalid prescriptions when members of its compliance team knew—at a minimum through their willful blindness—that the prescriptions (1) were invalid because they were written by pill-mill prescribers, (2) would be presented to Walmart pharmacies, and (3) would be filled as a consequence of actions the compliance team chose to take and not take. When the compliance team knew through their willful blindness, they were subjectively aware of the high probability that these three facts were true and took deliberate steps to avoid confirming the truth.

147. First, the compliance team had evidence available to it—and unavailable to pharmacists—that identified specific pill-mill prescribers. That information included Walmart's nationwide dispensing data that showed prescription-writing habits consistent with pill mills. It also included refusal-to-fill forms completed by pharmacists that reported glaring red flags. Other information came from pharmacists who sought help from the compliance team about how to handle particular prescribers' prescriptions. Through all this information, members of the compliance team knew that certain prescribers were pill mills whose controlled-substance prescriptions all were invalid.

148. Second, the compliance team also knew that individuals with prescriptions from known pill-mill prescribers would continue to bring their invalid prescriptions to Walmart. Multiple refusal-to-fill forms, for example, were submitted for the same pill-mill prescribers. Those forms showed that prescriptions for the same prescribers were being presented to many

different Walmart pharmacies, sometimes in different states.

149. Third, the compliance team knew that their decisions would cause prescriptions from these pill mills to be filled. They knew what policies would stop the steady stream of invalid prescriptions and which ones would let them flow. They repeatedly chose the latter, declining to share the information they knew about pill-mill prescribers, rejecting pharmacists' requests to blanket refuse prescriptions from those prescribers, and refusing repeated requests for help with specific situations and specific prescribers.

150. The compliance team's choices reflected a conscious decision to prioritize business goals, not compliance with the CSA. They made these decisions knowing that they were choosing not to stop the flow of invalid prescriptions into their stores and choosing not to stop them from being filled. The compliance team therefore knew that their pharmacies would continue to receive and fill invalid prescriptions.

a. Walmart's compliance team knew that Walmart pharmacists were receiving and filling prescriptions written by pill-mill prescribers practicing outside the usual course of professional practice.

151. As the compliance team's August 2013 training recognized, prescribers were contributing to the "problem of abuse and addiction" during the opioid crisis. Walmart's pharmacies were not immune from the effects of the crisis. As described below, the compliance team learned information about certain prescribers that was sufficient to conclude that those prescribers were pill mills and that their prescriptions were being presented and would continue to be presented to, and then filled by, Walmart pharmacies.

i. Compliance team members knew the identity of certain pill-mill prescribers and knew that their prescriptions were not issued in the usual course of professional practice.

152. The information obtained by the compliance team about pill-mill prescribers came

from various sources, including refusal-to-fill forms, emails from pharmacists, and dispensing analyses. Based on this information, compliance team members knew that certain prescribers were pill mills and that their prescriptions were invalid.

153. These team members included, at a minimum, those with specific responsibilities related to refusal-to-fill forms, such as B.N., from March 2011 through March 2015, and M.J., from October 2014 to April 2019.

154. Beginning in November 2013, B.N. was the leader of the refusal-to-fill project, the purpose of which was to establish a process for analyzing and internally reporting refusal-to-fill information. He also was responsible for monitoring the Health and Wellness email address used for refusal-to-fill reporting and for sending the information to DEA pursuant to the MOA. B.N. reported to G.C., a senior director on the team who was one of two leaders of the Controlled Substances Workgroup. From his management role, G.C. knew the content of the refusal-to-fill forms. In addition, he knew that the forms contained critical information about prescribers because, in May 2013, S.H., another senior director, sent G.C. a spreadsheet containing the content of refusal-to-fill information from two states, asking to discuss the data. G.C. was the sole leader of the Controlled Substances Workgroup when M.J. became Director of Controlled Substances in October 2014 and assumed responsibility for the refusal-to-fill project. In her new position, M.J. also knew that the refusal-to-fill forms contained information that pharmacists needed to properly exercise corresponding responsibility.

(a) Compliance team members received significant derogatory information about certain prescribers reported by Walmart pharmacists.

155. The compliance team received more than 90,000 refusal-to-fill forms from January 2012 through July 2015, and continued to receive thousands more forms thereafter.

From those thousands of forms, members of the compliance team were made aware of both the identity and the egregious practices of certain pill-mill prescribers—including prescribers who wrote prescriptions for drugs based on patients' drug-seeking requests rather than medical needs, prescribers who were writing prescriptions for the same drugs and dosages for large numbers of patients, prescriptions for cocktails of drugs known to be abused, and prescriptions for excessive quantities of controlled substances. From the volume of refusal-to-fill forms received about certain prescribers, their content, or a combination of both factors, the compliance team knew the identity of certain pill-mill prescribers. Many of these prescribers later were criminally convicted or lost their licenses, or both.

156. In addition to refusal-to-fill forms, pharmacists reported issues with pill-mill prescribers in emails sent to members of the compliance team, including R.I., M.J., T.K., D.M., B.N., C.R., and S.T., often asking for guidance about how to handle future prescriptions from those prescribers. These emails included clear reports that there was "just no medical need" for prescribers' prescriptions, that prescribers were under investigation and had been blocked by other pharmacies, and that they were "pill mills."

157. Paragraphs 236 through 445 below provide examples of the refusal-to-fill forms and emails received by compliance team members for just 20 of the reported pill-mill prescribers.

(b) Compliance team members also received other information about pill-mill prescribers from data on filled prescriptions and other monitoring.

158. Walmart's compliance team sometimes learned the identities and patterns of pill-mill prescribers from its analysis of dispensing data for stores, limited though that analysis was.

159. For example, the compliance team determined that D.C., whose prescribing habits

violated the Delaware Medical Practices Act, *see infra* ¶¶ 243-244, was responsible for 46 percent of a Delaware store's oxycodone-acetaminophen 10/325mg dispensing in May 2016. During that period, more than half—62 percent—of D.C.'s prescriptions for this drug were for quantities of 120 pills or greater, and 95 percent of his prescriptions were for controlled substances. Despite these red flags, Walmart compliance members shared these findings with only the one store. After May 2016, 17 different Walmart pharmacies continued to fill hundreds of D.C.'s prescriptions.

160. As another example, a suspicious order placed by a pharmacy in Wyoming in January 2017 for oxycodone-acetaminophen 10/325mg triggered an analysis of the store's dispensing data by M.J., who reported the results in an email copied to D.M. and S.T. One of the three top prescribers of that drug was responsible for 66 percent of the drug dispensed at that store. Not only did this (now-convicted) prescriber write large numbers of prescriptions for this drug, nearly all of them—93 percent—were for high quantities of 120 pills or greater. In addition, several of the prescriber's patients were receiving a widely abused cocktail of an opioid, a benzodiazepine, and carisoprodol, often referred to as the "trinity" combination.

161. Pharmacy audits conducted by Walmart also identified pill-mill prescribers. A Pembroke, North Carolina, pharmacy's fills for Endocet (a brand name of the combination drug oxycodone-acetaminophen) were audited in July 2013, for example, revealing that a particular prescriber, D.D.—who ultimately was sentenced to 20 years' imprisonment for CSA violations—was responsible for 21 percent of the store's fills for the drug. During a 90-day period, 79 percent of D.D.'s prescriptions were for high quantities of 120 and 180 pills per month. A pharmacist contacted the state medical board because of her concerns about the amount of controlled substances that D.D. prescribed. G.C. and T.K. were part of the email

exchange about the audit.

ii. Compliance team members also knew that Walmart pharmacists would continue to receive invalid prescriptions written by known pill-mill prescribers.

(a) Compliance team members received repeated reports that invalid prescriptions from pill-mill prescribers were being presented at Walmart pharmacies.

162. The compliance team knew that a single refusal, or even multiple refusals, from a single store would not stop the flow of prescriptions from pill-mill prescribers. They knew this fact because the team received multiple refusal-to-fill forms about the same prescribers, submitted by multiple pharmacists who worked at multiple pharmacies. For example, the team received reports about the following prescribers on dates no later than the following, and then received no fewer than the number of reports listed below:

Prescriber	Walmart Received a Report of Invalid Prescribing Through a Refusal-to-Fill Form No Later Than:	Minimum No. of Subsequent Refusals to Fill for the Same Prescriber:	Minimum No. of Pharmacies Subsequently Reporting Refusals to Fill:
F.T.	7/23/2012	115	26
G.G.	6/22/2012	134	11
J.I.	4/15/2012	164	27
M.M.	1/5/2012	260	33
P.T.	10/31/2012	208	6
R.M.	10/16/2012	259	103
S.K.	7/22/2013	98	11
V.S.	11/7/2013	116	8
W.W.	10/16/2012	180	14
Z.B.	8/29/2012	175	36

163. This pattern was the result, in part, of pharmacy shopping, a well-known red flag of diversion that Walmart recognized in its written policy manual. *See supra* ¶ 120. Because of the significant number of Walmart pharmacies, including multiple pharmacies in the same community, pharmacy shopping occurred not just between Walmart and competing pharmacies,

but also among Walmart's own pharmacies. In addition, this pattern was the result of the fact that pill-mill prescribers and the individuals who obtained the invalid prescriptions were persistent; the same pill-mill prescribers continued to write prescriptions and those prescriptions continued to be presented to the same stores, despite previous refusals.

164. Pharmacy shopping among Walmart stores was not merely a remote possibility. One market director, for example, described this pattern as a certainty. This director sought help from the compliance team with a particular prescriber who was a "mill for [o]xycodone Rx's" and who was under investigation by DEA. Because "these patients and prescriptions will simply move to another location," the market director wrote to S.T. in May 2014, "hoping we had a process for flagging doctors that are under investigation so all locations are aware?" The prescriber who prompted this market director's concerns pled guilty in 2019 to federal criminal charges for writing illegal prescriptions for oxycodone, admitting that he acted outside the usual course of professional practice and that there was no legitimate medical purpose for the drugs he prescribed.

165. The compliance team, including B.N., knew that pharmacy shopping occurred among Walmart's own stores. When B.N. learned in June 2015 that a prescriber's patients who were refused by a Las Vegas Walmart pharmacy had started going to a Walmart store in Pahrump, about one hour outside Las Vegas, he recognized that pharmacy shopping was the reason: "The reason these prescriptions are migrating to this store is because we are willing to fill the prescriptions. These patients are very well connected and they communicate where to go to get the prescription filled." Ultimately, that prescriber admitted in 2021 to the Nevada Board of Medical Examiners that he failed to adequately supervise his son, who was not a licensed medical practitioner and who prescribed controlled substances without determining whether they

were medically necessary.

166. Given that the opioid crisis was nationwide, the stream of invalid prescriptions was not confined to a particular region, and compliance team members knew this. "The issue of heavy writers of CII [Schedule II] and other Controlled Substance prescriptions comes up frequently across our trade areas," according to B.N. in January 2013. Similarly, when a pharmacist had trouble meeting demand for oxycodone 30mg, B.N. wrote, "[T]hat is not due to a shortage[;] it is due to the over prescribing of OXY 30mg in America."

167. And given the persistence of the opioid crisis, Walmart's compliance team knew that the problem of invalid prescriptions was not going away. As B.N. acknowledged in February 2015, "[t]hese bad actors will continue to write for controlled substances . . . ."

(b) Compliance team members knew that Walmart's policies directly affected the stream of invalid prescriptions received at Walmart's pharmacies.

168. Compliance team members knew not only that specific pill-mill prescribers' prescriptions continued to be presented at their pharmacies, but also that the compliance team had the ability to slow or stop, or, by contrast, encourage, the stream of invalid prescriptions by their policies. The fewer the controls they put in place, the more likely it was that invalid prescriptions would continue to be presented at their pharmacies. B.N., D.M., and S.T. were specifically informed of the direct impact of their policies in August 2013 by a market director who reported in an email to these managers that a group of Colorado Board of Pharmacy inspectors believed that Walmart had become a "funnel" for Schedule II controlled substances. This was the result of Walmart's "more liberal" policies compared to those of other retail chain pharmacies.

169. One of the policies that compliance team members knew affected the stream of

invalid prescriptions was its prohibition against blanket refusals. *See supra* ¶ 106. Had the team permitted pharmacists to blanket refuse all prescriptions from certain prescribers, that policy, once implemented by individual pharmacists, would have immediately stopped the flow of invalid prescriptions from those prescribers to pharmacists who issued blanket refusals.

170. The stream of invalid prescriptions also was the likely result of Walmart's business model, which depended on foot traffic through both its pharmacies and stores and depended on repeat customers. Walmart of course wanted these shopping habits to become fixed, and they did, for both those customers presenting with valid prescriptions and those without. As B.N. acknowledged, "[y]ou could Google Oxycodone and Suboxone and Sam's and they would tell you how to get these prescriptions filled at drastic savings. That is why many of these scripts migrate to Sam's clubs. I know this practice has stopped but the traffic and routines of these patients have already been established."

iii. Walmart's compliance team deliberately chose to avoid confirming that certain reported pill-mill prescribers' prescriptions were invalid and that Walmart pharmacists were continuing to receive and fill those prescriptions.

171. From the various sources of information described above, compliance team members knew that Walmart pharmacies were continuing to receive and to fill invalid prescriptions written by pill-mill prescribers. When they knew these facts based on their willful blindness, they were subjectively aware of the high probability of the truth of these facts and, as described below, deliberately chose to avoid confirming them.

172. These team members included, at a minimum, those with specific responsibilities related to refusal-to-fill forms, such as B.N., from March 2011 through March 2015, and M.J., from October 2014 to April 2019. From emails and meetings, other compliance team members, including G.C., R.I., T.K., D.M., C.R., and S.T., also knew that the forms contained pharmacists'

reports about prescribers and knew that the team was not using the information to learn about their pharmacies' fills of invalid prescriptions.

(a) Compliance team members chose not to analyze the alarming refusal-to-fill information submitted by pharmacists and instead prioritized "driving sales."

173. Information about pill-mill prescribers languished in the hands of the compliance team. The team acknowledged as early as August 2013 that such information could "help the Home Office help all of you identify trends observed throughout the nation that could be relevant to your exercise of professional judgment." However, those individuals failed to use the information to stop the filling of invalid prescriptions.

174. Indeed, the person entrusted with the responsibility for monitoring the refusal-to-fill forms, B.N., was dismissive about their value. When a field supervisor asked in February 2015 whether the compliance team "pull[ed] out any insights" from the information, B.N. answered, "The MOA that requires the reporting of the Refusal to fills expires in 30 days. We have not invested a great amount of effort in doing analysis on the data since the agreement is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time." By "patient awareness," B.N. was referring to the other services that Walmart pharmacies offered customers, such as immunizations.

175. B.N. also revealed his views of the opioid crisis in September 2014, when Walmart was asked to stock overdose kits. He noted that the items for the kits were "terribly expensive and non-returnable, so use caution when deciding to stock these items." He forwarded the email thread to C.R. with the comment, "More BS."

176. Other team members shared the view that Walmart's gatekeeping responsibilities, which it had voluntarily taken on when it sought DEA registrations for its pharmacies, were

somehow unfair. In September 2017, C.R. forwarded to R.I. a social media post that responded to the news that one of Walmart's competitors had instituted a seven-day limit on opioid prescriptions. This pharmacist opined that "it should NOT be the pharmacists' responsibility to be the Police, DEA, KGB, or Gestapo." C.R. described the post as follows: "Interesting take from someone on the news about [a competing chain pharmacy] limiting opioids to 7 day supply. This is from a forum . . . called 'Angry pharmacist' he is usually funny, but this time I think he hit the nail on the head."

177. With these attitudes as the backdrop for their decisions, the compliance team chose to make little use of refusal-to-fill information, even though they recognized the value in the information. In October 2013, a Controlled Substances Workgroup was created. Beginning the following month, G.C., a senior director on the compliance team, became one of two leaders of the workgroup. At the same time, the workgroup established as a goal the refusal-to-fill project, G.C. delegated the project to B.N., and the project's due date was April 30, 2014. One of the "success measures" of the project was to "[d]eliver a process for the analysis of refusal to fill data."

178. Under G.C.'s leadership, B.N. and the workgroup made little progress. Between December 2013 and July 2014, the workgroup held many meetings but took no concrete steps. By July 2014, with the April 30, 2014, due date obviously not met, the workgroup pushed the due date a full year, to April 30, 2015.

179. The compliance team did not meet its goal of establishing a process to analyze refusal-to-fill information by April 2015. Instead, the compliance team began its search in April 2015 for a Senior Controlled Substances Analyst whose responsibilities included the analysis of refusal-to-fill information. However, according to the job description, the analyst initially would

prioritize other projects and would turn to the refusal-to-fill analysis only later.

180. To the extent that the team used the refusal-to-fill information, they focused on the number of forms submitted by each store, instead of reading the pharmacists' comments explaining their refusals. This focus on process—whether pharmacists were completing the forms—led team members to ignore the substance of these reports from pharmacists, which described glaring red flags. For example, when B.N. learned in a November 2015 email that a store planned to stop filling for a doctor who called ahead to see what the pharmacy had in stock, had patients who had been "fired" by other doctors (including one with a known history of drug abuse), often was on the phone with the patients as they entered the store, and was suspected of operating out of his house, B.N. said there was "no evidence" to support the pharmacy's claim that the doctor's prescriptions lacked a legitimate medical purpose. B.N. made this assertion, despite the red flags reported by the pharmacist, because the pharmacy had submitted only one refusal-to-fill form for prescriptions the doctor had previously written.

181. Even if the number of refusal-to-fill forms were an adequate guide—on its own—to judging dispensing decisions, the compliance team knew stores did not consistently and uniformly comply with the requirement to complete a refusal-to-fill form. The compliance team members knew this because they tracked the number of forms after the process was moved to Archer. That analysis showed that some stores that previously had submitted refusals had submitted none through Archer. As of March 2016, approximately eight months after the move to Archer, about 1,138 stores had reported no refusals in Archer. M.J. conducted this analysis and shared it with B.N., C.R., and S.T.

182. Moreover, the team's monitoring was not consistent. For example, it took more than two years for M.J. to realize in June 2016 that a store had not reported any refusals since

January 2014. Even then, M.J. was focused on ensuring that the store documented its refusals, rather than asking the more fundamental question of whether the store was making appropriate fill decisions.

183. The prescription-writing patterns of multiple prescribers, including those discussed in detail below, *see infra* ¶¶ 236-445, clearly showed that these prescribers were acting outside the usual course of professional practice, but the signs were clear only if they were seen and read, and the compliance team deliberately chose to ignore them.

(b) Compliance team members deliberately avoided learning more from their pharmacists about reported pill-mill prescribers and gathering or analyzing other critical information about them, including even prescribers who were under investigation.

184. Not only did the compliance team members choose not to identify overall trends from the very concerning information they had about pill-mill prescribers, but they also generally did nothing to investigate individual prescribers. For example, until the prescriber review program began in or about February 2017, *see supra* ¶ 128, compliance team members failed to retrieve readily available public information showing that certain reported pill-mill prescribers faced administrative actions by state medical licensing boards and criminal prosecutions by state and federal authorities. They also often failed to contact other non-Walmart pharmacies that had decided not to fill prescriptions for reported pill-mill prescribers. In fact, according to some pharmacists, Walmart's compliance team often did not even take the most basic step of speaking with its own pharmacists who had refused to fill prescriptions of reported pill-mill prescribers.

185. The compliance team also sought to *reduce* the amount of information they received and to make it harder for pharmacists to communicate their concerns. In February 2017, the compliance team removed the comments field in the refusal-to-fill form, thus leaving the pharmacists with only a drop-down menu of pre-set options to explain their refusals. To

provide the details, pharmacists had to ask to be contacted by the compliance team. M.J., a director on the team, advised C.R., S.T., and B.N., with a copy to G.C., R.I., T.K., and D.M., of the change in a February 2017 email. She explained that the change would "prevent you from having the [sic] scan through numerous comments that may not be relevant."

186. The information being omitted, however, was the very information that would have identified certain prescribers as pill mills.

187. The change reflected a desire not to have anything in writing: "This [that is, the process requiring pharmacists to ask to be contacted when completing a refusal-to-fill form] is in place because Archer purposefully does not allow for free-form entry by the submitting pharmacist." Instead, pharmacists who asked to be contacted to provide additional details received an email instructing them not to reply in writing. *See supra* ¶ 131. Multiple members of the compliance team, including G.C., R.I., T.K., M.J., D.M., B.N., C.R., and S.T., participated or were invited to participate in drafting the email that would be sent to pharmacists.

188. Pharmacists wanted the comments field returned. In February 2017, a market director received feedback from his pharmacies and asked, "Could the comments field be retu[r]ned in Archer when refusing to fill a prescription?" M.J. claimed in her response that the comments field could not be added back. A regional director notified the entire compliance team in March 2017, using the team's "HW Practice Compliance" email address, asking, "Why was the comment field removed from the RTF? Would it be possible to have [it] added back in? They feel it was a benefit to be able to further explain the situation or concerns with the Rx." C.R. informed the regional director that the compliance team would accept the details of refusals only by phone.

189. Later, in February 2018, the compliance team did add a comments field to the

form used when a pharmacist wanted to blanket refuse prescriptions from a particular prescriber. But they did nothing to ensure that they would learn the details of pill-mill prescribers before any pharmacist decided to blanket refuse those prescribers. And, of course, the team had no assurance that every pill-mill prescriber would be the subject of a blanket refusal, in which case the team's choices meant that the team members never would learn the details about those prescribers.

190. In addition to minimizing the amount of information they received about pill-mill prescribers, members of the compliance team were uninterested in the details of government investigations of certain prescribers. In response to a market director in New Hampshire who sought direction in January 2013 regarding a physician who was under investigation, B.N., copying C.R. and R.I., observed that "[t]here are plenty of Dr's and Pharmacies under investigation including Walmart. I would not want patients to stop bringing their RX's to Walmart because of an investigation by the State Board or other regulatory agency." Even when DEA asked Walmart to voluntarily stop filling for a prescriber, B.N. believed that Walmart should not comply.

191. Only after DEA's search of a Walmart pharmacy in Texas did the compliance team revise POM 1311 in February 2017 to reflect the common-sense idea that the existence of an investigation of a prescriber is, at a minimum, relevant to evaluating the prescriber's prescriptions, adding as a red flag the following: "Prescriber is under investigation or has been disciplined for inappropriate prescribing of controlled substances."

192. But until the team reversed course, its messaging was so successful that pharmacists believed that the fact that a prescriber was under investigation was something they were not even permitted to consider. One pharmacist cautioned another against refusing a

suspicious prescriber's prescriptions based on an investigation: "We have Dr like that in this area and prof svsc told us we can not refuse rxs based on this information. If you have cause to believe there is not a valid pt Dr relationship. . that's a different story. But we can't refuse because he's under investigation. . . Don't want anyone to get in trouble."

193. Thus, despite all that they knew about reported pill-mill prescribers and Walmart's responsibilities as a DEA registrant, the compliance team routinely and deliberately chose not to gather or analyze available information about the reported prescribers.

b. Despite knowing that Walmart pharmacists were receiving invalid prescriptions written by pill-mill prescribers, Walmart compliance team members took actions that they knew would lead to Walmart pharmacists filling many of the invalid prescriptions by known pill-mill prescribers.

194. Knowing that the opioid crisis created a steady stream of invalid prescriptions that flowed regularly into Walmart's pharmacies, compliance team members could have stopped the pharmacies from filling those invalid prescriptions, fulfilling their role as gatekeepers. They had the authority to do so and knew that they did, as demonstrated by their selective deployment of that authority. *See supra* part II.A.2. Instead, the team adopted policies and created incentives that they knew would lead, and did lead, to Walmart pharmacies filling invalid prescriptions written by known pill-mill prescribers.

i. Compliance team members for years chose not to share with pharmacists—even in response to specific requests—critical information that they knew about pill-mill prescribers.

195. Under the CSA, any prescription written outside the usual course of professional practice is invalid. And since a pill-mill prescriber practices outside the usual course, all prescriptions from such a prescriber are invalid. Compliance with the CSA thus required refusal of known pill-mill prescribers' prescriptions. But rather than taking steps to ensure that those invalid prescriptions would be refused, the compliance team, for years, acted to keep the

information about pill-mill prescribers to themselves, leaving their pharmacists to make decisions in the dark.

196. As explained above, *see supra* part II.B.1.a.iii(a), for years, Walmart's compliance team did not make available to its pharmacists the refusal-to-fill information.

197. At most, B.N. periodically sent spreadsheets compiling refusal-to-fill information to divisional directors. However, those spreadsheets, like the spreadsheets sent to DEA, did not include the most informative part of the refusal-to-fill forms, that is, the pharmacists' comments detailing the pill-mill behavior that led to their refusals.

198. Although Walmart's compliance team recognized the need to disseminate refusal-to-fill information to its pharmacists, Walmart's compliance team did not consider the need to be urgent and thus took years to make it available. The dissemination of refusal-to-fill information was not treated as urgent even though the goal to "[d]etermine how to disseminate refusal to fill decisions and/or problematic prescribers and patients within the same trade area or to the entire corporate entity" was identified as a "key deliverable" of the Controlled Substances Workgroup that was formed in October 2013. *See supra* ¶ 177.

199. To disseminate information critical to filling prescriptions, Walmart had long used alerts to pharmacists in Connexus. Connexus contained multiple alerts prompting the pharmacist to evaluate safety issues, such as whether the prescription would result in duplicate therapy or a total dosage exceeding the maximum, a dangerous or problematic drug interaction, or disease contraindications.

200. When the compliance team finally made the refusal-to-fill information accessible to pharmacists, they did not use Connexus. Instead, in July 2015, the refusal-to-fill process was moved to Archer. That platform permitted pharmacists—for the first time—to search and view

refusal-to-fill forms that had been submitted company-wide.

201. However, the new Archer tool was meaningful only insofar as it was publicized and used, and the compliance team did not take steps to ensure awareness or use. When the team rolled out this new capability, they initially shared it in or about January 2016 with only certain field supervisors, with an instruction from director M.J. to "please don't send it to store level."

202. POM 1311 was not revised until March 2017 to include a reference to the refusal-to-fill information in Archer. Even then, the resource was simply listed without any direction or explanation. Thus, some pharmacists were not aware that this information was available.

203. Compliance team members, including M.J., knew that pharmacists were not using the refusal-to-fill information. M.J. was told in a January 2017 email that "a lot of pharmacists still do not go into archer or know a lot about it . . . ." In response to this and other comments about the refusal-to-fill process, M.J. asked,

> How could we push the information to pharmacies. For example a pharmacy may only fill a portion of the prescriptions from a high risk prescriber, so they might not notice something concerning. How could we tell them to monitor him closely, because they may not go out an[d] search Archer based on the prescriptions they are seeing[.]

204. The problem that M.J. observed—that a pharmacist who did not suspect a prescriber would have no reason to search the prescriber in Archer—was exacerbated by the fact that the refusal-to-fill information was not integrated into Connexus, and pharmacists did not receive automatic notifications alerting them to refusals-to-fill for the prescriber or patient. As director M.J. explained, Connexus and Archer did not "talk to each other." If a pharmacist wanted to know whether other pharmacists had refused to fill prescriptions for a patient or prescriber, the pharmacist would have to navigate out of the Connexus system, log into Archer, and manually conduct the refusal-to-fill search.

205. The unsuspecting pharmacist whom M.J. described in her January 2017 email was

exactly the person who needed to know about other pharmacists' refusals to fill for the prescriber and the reasons for those refusals. For years, however, the compliance team did nothing to ensure that those pharmacists would have the critical information they needed about pill-mill prescribers.

206. As late as July 2018, the refusal-to-fill information was not easily accessible to pharmacists. A director on the compliance team expressed the urgency of equipping pharmacists with this information:

> I wanted to take a moment and explain the purpose and need of the Refusal to Fill project that Rapid Response is working on. Currently, in the pharmacies, if the pharmacist makes a professional judgment, based on identified red flags, to not fill a prescription for a controlled substance, the pharmacist submits a refusal to fill form in Archer. These forms are collected and stored in Archer. However, pharmacists do not have easy access to this information, especially if the pharmacist is from another store. This information could be used to clear red flags, or identify red flags that may indicate that the prescription was not issued for a legitimate medical reason. In order to ensure the pharmacist is equipped to make the most appropriate decision, this information needs to be readily available. . . . Currently, pharmacists do not have easy access to this information to utilize in their professional judgment. The need is to get this project into the hands of the pharmacists as soon as we can.

207. Moreover, the compliance team not only chose for years not to adequately distribute refusal-to-fill information but also affirmatively refused specific requests for the information. In August 2015, for instance, after a store in Illinois was presented with prescriptions from Florida doctors, a pharmacist asked B.N. for a list of the "names of the Doctors/Prescribers that Walmart has the most 'Refuse to Fill' reports filed on or are known prescribers from the Florida-Kentucky oxycodone ring[.]" B.N. refused, saying, "Sorry but we cannot provide that information . . . . We are advised not to provide lists of prescribers to anyone other than law enforcement."

208. By choosing not to share or otherwise ensure that its pharmacists made decisions equipped with important information about prescribers, the compliance team left Walmart

pharmacists ignorant of the egregious practices of pill-mill prescribers reported by other pharmacists and thus caused them to make fill decisions without knowing the facts showing that those prescribers were acting outside the usual course of professional practice. The team did so knowing that, without this information, it was inevitable that Walmart pharmacists would fill invalid prescriptions written by reported pill-mill prescribers.

ii. When Walmart pharmacists identified pill-mill prescribers who were acting outside the usual course of professional practice, Walmart's compliance team members wrongly instructed pharmacists that neither they nor their pharmacies could blanket refuse to fill the prescribers' prescriptions.

209. Even when Walmart pharmacists were able to detect pill-mill prescribers, the compliance team actively prevented the pharmacists from blanket refusing to fill those prescribers' prescriptions.

210. Walmart's compliance team maintained this prohibition even though they knew that some prescribers themselves could be a red flag because of their prescribing practices. The "red flags document" and August 2013 training, *see supra* ¶¶ 113-116, recognized that a physician's prescribing practices could provide a reason not to fill a prescription. And yet Walmart's compliance team prohibited its pharmacists from making the only appropriate decision for a prescriber practicing outside the usual course of professional practice: refuse all of the prescriber's controlled-substance prescriptions.

211. The compliance team included this prohibition in its boilerplate POM 1311 response: "[N]o blanket refusals are allowed by the Boards of Pharmacy." POM 1311 (2011) also reflected the policy: "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not based on a valid prescriber-patient relationship or for a valid medical reason before refusing to fill."

212. Multiple compliance team members knew about the prohibition against blanket

refusals because they used or were aware of the boilerplate POM 1311 response. B.N. shared it with S.T., who forwarded it to C.R. Others, including G.C., R.I., T.K., and D.M., knew of the boilerplate after being copied on emails in which the boilerplate was used as a response to pharmacists' inquiries.

213. By clearly prohibiting blanket refusals, the compliance team members knew they were creating a bias toward filling prescriptions, thus making it more probable that pharmacists would fill invalid prescriptions. And, in fact, pharmacists did fill invalid prescriptions written by pill-mill prescribers after being reminded that they were prohibited from blanket refusing prescriptions, however egregious the prescribers' conduct. *See infra* ¶¶ 473, 540.

214. Walmart's 2015 revision to POM 1311 eliminated its express prohibition on blanket refusals, but the POM still instructed pharmacists to assess every prescription individually: "A pharmacist must make an individual assessment of each prescription to determine if the prescription is written for a legitimate medical purpose." The team thus revised the POM in such a way that it communicated to pharmacists that they were still prohibited from adopting blanket refusals, even if an explicit prohibition was not mentioned in the POM.

215. Indeed, the compliance team continued to advise pharmacists that they were *not* permitted to blanket refuse a particular prescriber's prescriptions. B.N. did so at least as late as October 6, 2016, when a pharmacy manager asked, "Is it okay to blanket refuse for a doctor who we have documented evidence of competency/ethical concerns?" B.N. responded, "A[t] this time there is not an option to blanket refuse any prescriber."

216. This prohibition against blanket refusals was not, as Walmart for years insisted, required by law. Despite its strong and unequivocal assertion that blanket refusals were prohibited by state boards of pharmacy, the question was in fact one that Walmart had not

answered. For example, in December 2013, the Controlled Substances Workgroup, *see supra* ¶ *177*, added the issue as a "key deliverable": "Engage key stakeholders to determine if pharmacists may exercise their discretion to impose blanket refusals." And, as early as 2013, the compliance team knew that other chain pharmacies permitted blanket refusals.

217. Walmart's prohibition on blanket refusals stemmed instead from its concern that it would be sued by prescribers and its choice to prioritize addressing that risk over the risk of non-compliance with the CSA. Even when Walmart permitted its pharmacists to implement their own blanket refusals, it prohibited them from communicating the reasons for their decision in writing and instructed them to inform other pharmacists at the pharmacy "in an oral communication." Pharmacists were specifically instructed not to post any lists of prescribers in the pharmacy or in Connexus, the system used to fill prescriptions and thus the mechanism by which another pharmacist would most likely be alerted. Similarly, the pharmacy manager and other field supervisors who oversaw the blanket refusal process were instructed, "Please do not document or take notes of the conversation with your pharmacists."

218. Contrary to the compliance team's instructions, blanket refusals were permitted under state law. Indeed, Walmart began implementing a broader and mandatory form of them on a nationwide basis in or about January 2017. When imposed, these home-office-initiated corporate blocks prevented pharmacists from filling certain problematic prescribers' prescriptions nationwide.

219. By forbidding blanket refusals, Walmart's compliance team knew they were encouraging pharmacists to fill, rather than question, prescriptions. For example, a pharmacist in Georgia believed that a prescriber was "over-prescribing" multiple Schedule II controlled substances and oxycodone 30mg in particular. In March 2013, DEA was investigating the

prescriber and his clinic and had asked the pharmacy not to fill for the clinic. But the pharmacist was instructed that she could not comply with DEA's request for a blanket refusal. Going forward, the pharmacy manager said that they would "make every effort to fill these scripts now unless overdosage amounts are prescribed." But simply avoiding overdose amounts was insufficient to meet Walmart's compliance obligations. While prescriptions for overdose amounts certainly were invalid, invalid prescriptions included more than just prescriptions that would cause an overdose.

220. By prohibiting blanket refusals, the compliance team chose a policy that discouraged pharmacists from refusing prescriptions written by pill-mill prescribers even when they were able to identify those pill-mill prescribers on their own.

iii. While withholding information and tools necessary for its pharmacists to properly exercise their corresponding responsibility, compliance team members simultaneously chose not to act on the information and authority that they possessed.

221. The compliance team chose to withhold, and eventually make available, though not meaningfully, information that would have revealed to its pharmacists that certain prescribers were pill mills. Then, when pharmacists had personal knowledge about prescribers, leading them to conclude that all their prescriptions should be rejected, the compliance team prohibited pharmacists from responding to that information with a blanket refusal. Moreover, the compliance team could have itself used the derogatory information to ensure that these pill-mill prescribers' prescriptions would not be filled, but for years it chose not to use the information, resisting pharmacists' requests that Walmart corporately block certain prescribers nationwide.

222. The value of the compliance team making corporate-wide decisions about certain prescribers was obvious to some pharmacists, who requested such action but were rebuffed. In September 2013, for example, a pharmacy manager identified G.H. and R.M. as pill-mill doctors

and assumed that the situation required "corporate to decide on what to do." In the meantime, the pharmacist said the store might start refusing their prescriptions because "I have too much invested in my career and family to continue to risk it." B.N. replied with the boilerplate POM 1311 response and added, "We are not allowed to blanket refuse to fill prescriptions from a prescriber's office." G.H. and R.M. lost their medical licenses under circumstances that proved the pharmacist correct in concluding that a corporate block was warranted. *See infra* ¶¶ 276-289.

223. For years, Walmart persisted in leaving its pharmacists on their own. In October 2016, a Minnesota pharmacist directly criticized this policy: "I'm not sure I feel comfortable filling any prescription written by a doctor who thinks it's ok to prescribe this way. Pharmacists have an obligation to ensure that controlled substances are being used and prescribed appropriately. The countries [sic] prescription drug abuse problem is well documented and it's prescribers like these that are at the heart of the problem. We need to have a better system in place to protect us as pharmacists and Wal-Mart as a company from liability associated with this type of prescribing. I don't think 'pharmacist discretion' is enough to protect us."

224. Although Walmart had not issued any corporate blocks in 2016, when the Minnesota pharmacist criticized Walmart's policy, the compliance team had begun to consider implementing a corporate block program. In an October 2016 draft letter to the field about the program, director M.J. acknowledged that "we have access to information at the Home Office that is not available to our pharmacists" and the home office had "identified a very limited number of prescribers whose controlled substance prescribing practices are not indicative of prescribing controlled substances for legitimate medical purposes." M.J. also wrote that the compliance team would use the refusal-to-fill reports in Archer to consider which additional prescribers to block. When the team decided to corporately block prescribers, the decision was

to do so for "a very limited number [of] prescribers (2 prescribers initially)." As explained above, *see supra* ¶¶ 127-128, the first of the corporate blocks was implemented in January 2017.

225. Establishing the block was technically simple, involving just a computer "edit" that was tied to the prescriber's DEA number and National Provider Identification number. Any pharmacist who attempted to fill a prescription for that prescriber would trigger a message in Connexus that fills were prohibited.

226. Even after they started corporately blocking certain prescribers' prescriptions, the compliance team remained unresponsive to requests from pharmacists for what one described as "home office support" in the form of a corporate block. According to B.N. in a February 2017 email, "it takes 100's of RTF's to be considered for a Corporate Block," so "[i]t is a huge deal and we only have [a] handful of DR's that have been issued a Corporate block."

iv. In addition to withholding key information and prohibiting blanket refusals, compliance team members denied specific requests from pharmacists for direction and the tools necessary to identify invalid prescriptions.

227. The decisions regarding refusal-to-fill information, blanket refusals, and corporate blocks all reflected a decision to leave pharmacists on their own. Consistent with that approach, the compliance team regularly declined specific requests for help.

228. Instead of responding to pharmacists' specific questions, compliance team members most often simply relied on the boilerplate POM 1311 response whenever questions about professional judgment arose. They used it even though it simply parroted the standard, written policies and even though it often was insufficient to address pharmacists' concerns. As a pharmacist put it simply in March 2013, "SOP is not enough."

229. For example, in January 2013, the pharmacy staff in Grants Pass, Oregon, sought help with a prescriber who wrote an "astonishing" volume of narcotic prescriptions, creating a

"revolving door of scripts." B.N. simply referred the pharmacists to the "multiple POMs available to assist" and refused the pharmacy staff's request for an analysis of the prescriber's controlled-substance prescriptions.

230. The "revolving door of scripts" that the Walmart pharmacists observed led to the one-year suspension of the prescriber's prescriptive authority for Schedules II though IV controlled substances in May 2013 by the Oregon State Board of Nursing after their investigation established that the prescriber "prescribed significant amounts" of narcotics and benzodiazepines after failing "to properly assess and document client needs."

231. Similar questions continued for years. In July 2015, compliance managers C.R. and M.J. learned that Walmart's competitors had stopped filling oxycodone 30mg prescriptions from certain pain management doctors. Three Walmart pharmacies in New Jersey were concerned about the volume of oxycodone customers coming into their stores. C.R., copying M.J., responded with the boilerplate POM 1311 response.

232. In addition to seeking guidance about specific, challenging situations, pharmacists asked for more tools, such as a checklist similar to the one that a competing national pharmacy chain had adopted for its pharmacists. The checklist listed questions to answer and steps to take before dispensing certain high-risk drugs. In May 2013, a market director asked D.M., a senior director on the compliance team, whether Walmart would adopt something similar because, "[a]s you know, the Las Vegas area is having problems with pill mills and oxycodone prescribing." D.M. noted that Walmart had its POM and red-flags document, but otherwise "[w]e are leaving it to the rph [pharmacist] judgment." D.M. forwarded the request to senior directors G.C. and T.K., noting that "[s]everal people" had sent the checklist in.

233. By often declining to provide guidance or opinions even when specifically asked,

Walmart's compliance team turned "independence" into isolation, even though the compliance team recognized in the August 2013 "red flags" document that pharmacists' peers were among the resources available to help pharmacists exercise their corresponding responsibility.

c. Kept in the dark about key information regarding known pill-mill prescribers and operating under policies and directions that created a bias toward filling rather than refusing, Walmart pharmacists filled thousands of invalid prescriptions written by those prescribers.

234. The cumulative and inevitable result of the compliance team's decisions was that Walmart pharmacists filled thousands of invalid prescriptions. Unsurprisingly, pharmacists who were unfamiliar with critical information about reported pill-mill prescribers—and who generally were discouraged from refusing prescriptions—often filled invalid prescriptions written by those prescribers.

235. Below are 20 examples of the numerous prescribers whose egregious and unlawful prescribing practices were known to Walmart's compliance team members. These members included, at a minimum, those with specific responsibilities for the refusal-to-fill forms and process, such as B.N., from March 2011 through March 2015, and M.J., from October 2014 to approximately April 2019. The examples are organized in alphabetical order by the prescribers' initials. In each example, Walmart pharmacists repeatedly recognized and reported to Walmart's compliance team members that a particular prescriber was issuing prescriptions while acting outside the usual course of professional practice. In each example, Walmart compliance team members knew that its pharmacists were continuing to be presented with the prescriber's prescriptions, and they chose to act and not act in ways that led to the filling of more invalid controlled-substance prescriptions from the same prescriber.

D.C.: "95% of the prescriptions from this prescriber are for controlled substances"

236. D.C. was a doctor of osteopathic medicine who practiced in Wilmington and Newark, Delaware. He prescribed excessive doses of opioids without appropriately discussing the risks with his patients, monitoring his patients, or incorporating other treatments. D.C. was known for prescribing Percocet (oxycodone-acetaminophen) after performing what one person described as the "most trivial" of exams.

237. In 2014 and 2015, a Walmart pharmacist at Store 5436 in Wilmington, Delaware, refused to fill prescriptions written by D.C. because he identified unresolved red flags, including doctor shopping ("Checked PMP [prescription monitoring program] and saw multiple doctors prescribing similar medications." "Pt [patient] had received scripts for [P]ercocet from Dr. [C.], Dr. [Y.], and Dr. [W.] in the past two months for 20-30 day supplies.") and early refills ("Refilled early too many times … Pt says purse was stolen in [D]ecember leading to an extra fill but could not explain the other fills. Pt had filled [X]anax prescriptions 5 times in [D]ecember and twice in [J]anuary.").

238. On May 19, 2016, M.J. reported to DEA that Store 3802 in Middletown, Delaware, had placed a suspicious order for oxycodone-acetaminophen 10/325mg. She noted that D.C. prescribed 46 percent of the oxycodone-acetaminophen 10/325mgdispensed at this pharmacy. Another 11 percent of the oxycodone-acetaminophen 10/325mg dispensed at this pharmacy was prescribed by a physician's assistant practicing in D.C.'s office under his supervision.

239. M.J. also noted that 95 percent of the prescriptions written by D.C. were for controlled substances, and that 81 percent of what he prescribed was oxycodone-acetaminophen 10/325mg. She reported that for nearly two-and-a-half years, from January 1, 2014, through

May 19, 2016, Store 3802 had not reported a single refusal to fill.

240. The high volume of oxycodone-acetaminophen prescriptions dispensed by Walmart was not limited to Store 3802. During the Dispensing Violations Period, Walmart pharmacies dispensed approximately 440,134 oxycodone-acetaminophen tablets to D.C.'s patients, approximately 39,467 of which were dispensed at Store 3802.

241. Even after M.J. reported a suspicious order to DEA and learned that 81 percent of D.C.'s prescriptions were for a single opioid medication at a single strength—oxycodone-acetaminophen 10/325mg—Walmart pharmacies continued to fill this same prescription written by D.C.

242. By May 19, 2016, Walmart's compliance team, including at least M.J., knew that D.C.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They finally corporately blocked D.C. on May 1, 2017. In the interim and even a few months after implementing the central block, the team chose to act and not act in ways that led to the filling, from May 19, 2016, through July 12, 2017, of approximately 574 of D.C.'s invalid controlled-substance prescriptions, including approximately 365 oxycodone-acetaminophen 10/325mg prescriptions.

243. On August 2, 2019, the Delaware Division of Public Health announced that the Delaware Secretary of State had suspended D.C.'s medical license and controlled-substance registration, following an investigation into his prescribing and treatment practices.

244. After a multi-day hearing, the chief hearing officer found that D.C. had routinely prescribed controlled substances to two undercover officers and eight patients in violation of multiple provisions of Delaware's Medical Practice Act. The hearing officer found that D.C. prescribed controlled substances without conducting a meaningful initial evaluation or

examination of the patients and without discussing the risks and benefits of using the controlled substances, including the risk to the fetus when prescribing controlled substances to a pregnant patient. The hearing officer also found that D.C. documented in his chart physical examinations, complaints, and discussions that were inconsistent with what the individuals testified had occurred at the visits.

F.B.: "Always writes excessive quantities for all of his patients"

245. F.B. was a doctor who practiced at various locations in and around Savannah, Georgia, including a clinic that specialized in footwear for diabetics. He prescribed massive quantities of controlled substances, including the trinity combination of an opioid, a benzodiazepine, and carisoprodol. In fact, F.B. prescribed this dangerous cocktail more frequently to Medicare patients than did any other physician in the United States. F.B. accepted only cash for his office visits. He falsely claimed to work for the Department of Justice and displayed a fake police badge to intimidate patients. F.B. also exploited female patients and coerced some of them into providing sexual favors in exchange for controlled substances.

246. As early as June 2012, Walmart pharmacists expressed their concerns about F.B. to Walmart's compliance team. On June 6, 2012, a Walmart pharmacist working at Store 635 in Savannah, Georgia, refused to fill a prescription for carisoprodol 350mg, reporting to the compliance team that "DR[.] [F.B.] prescribed A MONTH SUPPLY OF controlled drug (NOT a PAIN CLINIC)."

247. On September 27, 2013, a pharmacist at Store 605 in Savannah, Georgia, recognized that F.B. was a "suspicious md" and that the individual seeking to fill the prescription "currently sees a pain management doc[to]r so she should not be filling [oxycodone-acetaminophen 10/325mg] from this general prac[ti]tioner." The pharmacist also commented that Store 605 generally did not "fill C II [Schedule II] prescriptions from this doctor because he

has written suspicious prescriptions in the past." The following month, another pharmacist at Store 605 wrote that F.B. was "writing outside of his scope of practice." Store 605, however, continued to fill F.B.'s prescriptions. From January 1, 2014, through December 19, 2016, Store 605 filled approximately 91 controlled-substance prescriptions written by F.B., including approximately 30 Schedule II controlled-substance prescriptions.

248. In 2014, Walmart pharmacists reported that F.B. "is known to write multiple controls for large quant[itie]s" and "always writes excessive quantities for all of his patients."

249. In numerous instances, beginning as early as February 2013, Walmart pharmacists complained about their inability to contact F.B., writing that "[i]t would be hard to verify the patient prescriber relationship since this office lacks open communication with our pharm[]acy via phone," F.B. "won[']t return messages to verify rx," and he "is impossible to get in touch with."

250. In February 2014, a pharmacist at Store 4556 in Savannah, Georgia, refused to fill a prescription for customer B.W. for oxycodone-acetaminophen 10/325mg. On the refusal-to-fill form, she recounted a conversation she had had with F.B.: "He asked why I needed to verify a class 3 narcotic …. When I told [F.B.] that generic Percocet was a class 2 narcotic his response to me was, 'Oxycodone with Acetaminophen is a class 3 narcotic not a class 2 narcotic, you should be ashamed of yourself that you do no[]t know this. I would not have prescribed it if it was a schedule 2 narcotic.' Based upon the fact that [F.B.] is not even aware of the medication he is prescribing (and he prescribes it frequently) I cannot ethically fill the prescription."

251. As other pharmacies in Savannah stopped filling F.B.'s prescriptions, individuals turned to Walmart to get them filled. In June 2015, a pharmacist at Store 605 reported to the compliance team that "[e]ach weekend – we are beginning to see [an] influx of the same

prescriptions written for MANY patients from [F.B.] …. Each weekend, at least 10 patients call/come in pharmacy with Percocet 10/325 #120, Xanax 2mg #90, Adderall 30mg #90 and sometimes Soma 350mg #90." The pharmacist also told Walmart's compliance team that "[o]ther pharmacies in our area (ie-Kroger) are no longer taking any of [F.B.'s] prescriptions …."

252. By September 27, 2013, Walmart's compliance team, including at least B.N., knew that F.B.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. For years, until the team corporately blocked F.B. on January 16, 2017, they chose to act and not act in ways that led to the filling, from September 27, 2013, through January 5, 2017, of approximately 800 of F.B.'s invalid controlled-substance prescriptions.

253. From September 30, 2015 (at which time Walmart's compliance team members knew that F.B.'s prescriptions were invalid), through January 31, 2017, the average Walmart customer filling F.B.'s prescriptions received a high dose of opioids, equivalent to a daily dosage of 90 MME. According to the Centers for Disease Control ("CDC"), many patients do not experience benefit in pain or function from increasing dosages over 50 MME, but they are exposed to progressive increases in risk as dosage increases. Also during this time period, Walmart dispensed 95 trinity combinations of an opioid, benzodiazepine, and muscle relaxant, and 282 combinations of an opioid and benzodiazepine, all prescribed by F.B.

254. In October 2019, a federal jury convicted F.B. on multiple counts of unlawful dispensing of controlled substances and healthcare fraud. F.B. was sentenced to 20 years in prison.

F.T.: Prescribed "too many [drugs] for one person to take"

255. F.T., an orthopedist, operated, with another individual, a pain management clinic

with offices in Tampa and Punta Gorda, Florida. F.T. rarely conducted physical or diagnostic examinations of his patients, ignored signs of drug diversion, and prescribed excessive amounts of opiates, including oxycodone, hydrocodone, hydromorphone, and morphine.

256. During the investigation of F.T., he and his business partner asked an undercover agent to smuggle a Hungarian national into the United States. In return, F.T. prescribed the agent an increased amount of oxycodone and hydromorphone, and F.T.'s business partner paid the agent $5,000 in cash. F.T. instructed the agent to fabricate an injury to justify the increased amounts of opioids and explained to the agent how to falsify his patient history.

257. Between July 2012 and September 2013, in refusal-to-fill forms submitted to Walmart's compliance team, Walmart pharmacists reported that they had refused to fill prescriptions after identifying multiple unresolved red flags regarding F.T. For example, pharmacists reported that F.T.'s patients appeared impaired and had used multiple pharmacies, including one individual who had been to more than 10 pharmacies during the preceding year. Pharmacists also refused to fill prescriptions because F.T. had ordered inappropriate quantities or combinations, such as combinations that posed the risk of respiratory depression and, in one instance, a quantity of Schedule II drugs that was "too many … for one person to take."

258. During the same period, at least five different pharmacists at different Walmart pharmacies reported, in at least 12 refusal-to-fill forms, that they had refused prescriptions because F.T.'s practice, the customer's residence, or both were outside the store's area.

259. According to reports from Walmart pharmacists to the compliance team, two different customers told pharmacists in December 2013 and May 2014 that they needed their medications from F.T. to prevent withdrawals. One of those individuals, who presented a methadone prescription, also had oxycodone in her fill history and presented prescriptions for

both herself and her husband. The other customer would frequently come in with several other individuals who, a pharmacist reported, "always appear high."

260. Reports of F.T.'s inappropriate prescribing practices continued in 2015, with pharmacists reporting, in January and May 2015, prescriptions issued by F.T. for quantities exceeding Walmart's internally set limits for methadone 10mg and for inappropriate combinations of opioids and methadone.

261. By June 26, 2013, Walmart's compliance team, including at least B.N., knew that F.T.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from June 26, 2013, through November 18, 2015, of approximately 1,284 of F.T.'s invalid controlled-substance prescriptions, including approximately 216 prescriptions paid for in cash. As Walmart recognized in POM 1311 (2015), a cash payment for a controlled-substance prescription is a red flag, particularly when the customer has insurance, because often insurance covers at least a portion of the cost of a valid prescription.

262. In December 2017, F.T. was sentenced to 12 years and seven months in prison after being tried and found guilty of causing the dispensing, without a legitimate medical purpose and not in the usual course of professional practice, of oxycodone, hydromorphone, morphine, and hydrocodone.

G.G.: "gives patients what they want and [does] not practice real medicine."

263. G.G., an osteopathic physician who practiced in Oakland City, Indiana, has a record of criminal and professional misconduct dating back to 2005. That year, the Medical Licensing Board of Indiana ("MLBI") suspended his osteopathic physician's license on an emergency basis, finding that his practice would present a "clear and immediate danger to the

public health and safety" if allowed to continue because he had allowed an unlicensed individual to prescribe drugs using G.G.'s DEA registration number and to treat G.G.'s patients. G.G. had hired that individual knowing that the individual was not licensed to practice medicine and had paid him $20 per hour.

264. G.G. also resolved the MLBI action in 2006 by agreeing, among other things, to the indefinite probation of his medical license. The probation, however, did not have a substantial effect on his ability to practice medicine or prescribe controlled substances.

265. In May 2011, in an interview with law enforcement officers, G.G. admitted providing medical treatment to his live-in housekeeper, with whom he was in a romantic relationship. He also admitted knowing that she was addicted to controlled substances and prescribing hydrocodone to her when she experienced withdrawal symptoms.

266. In October 2015, the MLBI ordered G.G.'s medical license indefinitely suspended and prohibited him from applying for reinstatement of his license for a minimum of three years. The MLBI found, among other things, that G.G. "prescribed and/or administered narcotic controlled substances to [the housekeeper], a known drug addict and other patients without objective evidence of medical necessity for the prescribed narcotic medications"; and that he prescribed and/or administered narcotic controlled substances to patients, including the housekeeper, "outside the safe and generally accepted medical principles and protocols regulating the practice of medicine."

267. On November 29, 2013, a Walmart pharmacist at Store 2563 in Paoli, Indiana, reported to Walmart's compliance team that G.G. had been "[b]anned companywide by [a competing retail pharmacy] and most local pharmacies near where he practices in Oakland City which is nearly 2 hours from this location." The pharmacist also reported that G.G. had a history

of "inappropriate practices" and was "on a watchlist with the Office of the Inspector General for the state of Indiana." The pharmacist therefore refused to fill prescriptions for Lortab and Xanax for patient S.E.

268. The compliance team did not disseminate this information about G.G., and Walmart pharmacies continued to fill G.G.'s prescriptions. In fact, a different Walmart pharmacy, Store 1162 in Washington, Indiana, filled S.E.'s two previously rejected prescriptions for Lortab and Xanax. Thereafter, Store 1162 and another Walmart pharmacy, Store 492 in Vincennes, Indiana, continued to dispense alprazolam (brand name Xanax) and hydrocodone-acetaminophen (brand name Lortab) to S.E. until March 2015.

269. On December 10, 2013, G.G. himself stated explicitly to the pharmacist-in-charge at Walmart Store 1263 in Evansville, Indiana, that he prescribed what patients wanted, not what they medically needed. As the pharmacist-in-charge reported in the refusal-to-fill form for customer B.M., "[d]octor declared that he knew it [Ambien 10mg prescription] was above the recommended dose and he couldn't convince the patient to stop taking it. Doctor wrote the rx due to that[']s what the patient [B.M.] wanted."

270. On the same day, a different Walmart pharmacy in Evansville, Store 1341, filled B.M.'s zolpidem (brand name Ambien) prescription. Store 1341 later filled 14 more zolpidem prescriptions for B.M.

271. In April 2014, on a refusal-to-fill form, a pharmacist from Walmart Store 1263 in Evansville, Indiana, reported that "most other pharmacies will not fill [G.G.'s] scripts [prescriptions]" and described G.G. as a "sketchy doctor" who "has been under investigation with the DEA." The same month, a pharmacist at Walmart Store 870 in Jasper, Indiana, reported to Walmart's compliance team, on a refusal-to-fill form, that G.G. "is known in a wide area for

weak prescribing practices concerning controlled substances. Drug seekers are the majority of his clientele." The pharmacist added that "there is a lot of diversion stemming from [G.G.'s] practice" and that "many of the medications being written for are being sold to the highest bidder."

272. In May 2014, the pharmacist-in-charge of Walmart Store 1263 once again reported to Walmart's compliance team that G.G. is "known in the area as a pill shop doctor and give[s] patients what they want and [does] not practice real medicine." The pharmacist-in charge also reported that "[b]esides [W]almart no other pharmacies in the tr[i]-state will fill for the md."

273. Walmart's compliance team was again alerted to G.G.'s apparent disregard for his patients' health when, in September 2014, a Walmart pharmacist at Store 1263 attempted to validate prescriptions for Adderall and Suboxone (brand name of the drug combination of buprenorphine and naloxone). In a refusal-to-fill form, the pharmacist explained that the patient was getting 30-day supplies of Adderall and Suboxone about every two weeks. She reported that the "patient looks like they are abusing the meds and the dr doesn't seem to care."

274. The warnings continued into 2015 on refusal-to-fill forms submitted by pharmacists at Walmart Store 870. From January 2015 to April 2015, pharmacists at that store reported the following about G.G.: "questionable doctor"; "has a lot of [M]edicaid patients that he should NOT be prescribing for"; and a "[p]ill mill" who "regularly writes for controlled medications for cash paying customers."

275. By November 29, 2013, Walmart's compliance team, including at least B.N., knew that G.G.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from November 29, 2013, through September 27, 2015, of approximately 3,566 of

G.G.'s invalid controlled-substance prescriptions, including approximately 629 paid for in cash.

G.H. and R.M.: "well known as a pill mill"

276. R.M. was the president and medical director of a cash-only clinic in Roland, Oklahoma, known as the "Wellness Clinic." G.H. practiced at the clinic. R.M. admitted that he managed the clinic "like a pill mill that herded patients through . . . and prescribed [controlled and dangerous substances] in large quantities based upon little to no physical examination or with no legitimate medical purpose." Local law enforcement reported that a lot of prescriptions found "on the street" came from the clinic. Patients recalled being asked by other patients whether they wanted to sell their pills. The clinic's patients came from at least 10 states, some traveling as far as 1,800 miles round-trip.

277. G.H. would see 50 to 60 patients per day. He made no attempt to treat pain through means other than prescribing controlled substances, and he would not attempt to decrease the dosages of controlled substances prescribed to his patients. G.H. ignored warning signs that patients were abusing their prescriptions.

278. On February 21 and 22, 2013, the pharmacy manager at Store 388 in Fort Smith, Arkansas, told B.N. about her concerns with the Wellness Clinic. She explained that "the only reason these high quantities would be needed are for addiction or diversion." She further admitted that she "could not justify a patient need for these medication[s] if questioned in court or by the DEA." The red flags that led to this conclusion were alarming in their number and severity:

- "Other chain and independent pharmacies in the area have stopped accepting prescriptions from this clinic, which is causing them to funnel in to our WalMart stores. Although a rise in business is good, this isn't the type of business we want."

- The clinic was "continually writing prescriptions for large numbers of multiple narcotic pain reli[e]vers."
- The store had experienced a 545 percent increase in oxycodone 15mg and a 97 percent increase in oxycodone 30mg dispensed for this clinic from October 2011 to October 2012. Prescriptions of morphine, both immediate and extended-release, and of methadone also had "sky rocketed."
- "[I]t is not uncommon for a patient to get #224 Methadone 10[mg], #168 Oxy 15[mg], #168 Oxy 30[mg], and then also some Hydrocodone, Soma, and XANAX, possibly also throw in one or 2 different Morphine Prescriptions."
- "A high percentage of these customers seem suspicious and some times even lie about being shorted medication . . . ."
- "They also flood our phone lines daily asking if we have sufficient quantities of OXY/ROXI and such."
- Speaking for herself and four colleagues, the pharmacy manager said that "[n]ot a single one of us ever feel comfortable about filling these prescriptions, and if questioned, we wouldn't be able to justify this type of prescribing."

279. Other pharmacies had stopped filling for the clinic, and the pharmacy manager felt "that it is imperative that we follow suit." Otherwise, "[i]t will look bad if we are the ones allowing these drugs to be abused or even on the street." In his reply, B.N. seemed to agree with the conclusion that the prescriptions should be refused, but he also reminded the manager that blanket refusals were prohibited and that a refusal-to-fill form was required for each refusal in the event that the customer or prescriber filed a complaint.

280. Additionally, Walmart pharmacists repeatedly reported that G.H. refused to

provide verification for opioid prescriptions. For example, a Walmart pharmacist at Store 2744 in Fort Smith, Arkansas, reported to Walmart's compliance team in March and April 2013 that G.H. refused to verify an oxycodone 30mg prescription when contacted and went so far as to block the pharmacy's telephone number.

281. Pharmacists also submitted refusal-to-fill forms to Walmart's compliance team for specific prescriptions issued by R.M. These prescriptions, which were presented to pharmacies at Store 380 in Waldron, Arkansas, and Store 55 in Booneville, Arkansas, showed multiple red flags that the pharmacist could not resolve, in that (a) they were written by an out-of-state prescriber; (b) one of R.M.'s patients had just been arrested for "delivery of Oxy[C]ontin" when he presented a prescription in August 2013 for oxycodone, methadone, and Valium; and (c) a husband and wife both presented prescriptions in April 2014 from R.M. for high doses of controlled substances that presented a significant risk of respiratory depression.

282. By September 2013, the pharmacy manager at a different Walmart store in Fort Smith, Arkansas, Store 8134, was sufficiently concerned about the prescribing practices of the doctors at R.M.'s clinic that he reached out to a Walmart market manager in the Health and Wellness Division. The pharmacy manager explained that "the problem" with R.M.'s clinic had "grown over the last 2 years," and that he was "feeling more uncomfortable about all scripts that come from" the clinic. He wrote, "[D]epending on how long it might take co[r]porate to decide on what to do, we might start to refuse to fill prescriptions for some patients. I have too much invested in my career and family to continue to risk it." He identified both G.H. and R.M. as the doctors responsible for the clinic's improper prescribing.

283. The market manager forwarded the pharmacy manager's email to Walmart's compliance team. In reply, B.N. stated that pharmacists should exercise their independent

judgment and refuse a prescription they deem invalid, but he also stated that Walmart had a policy that prohibited a blanket refusal to fill on any particular prescriber.

284. In April 2014, a pharmacist at Store 380 in Waldron, Arkansas, reported, in a refusal-to-fill form for prescriptions written by R.M., the store's problems with drug-seekers from the clinic: "They like [to] come during the lunch break for the pharmacy, they are extremely impatient (if you tell them 2 hours they check on the prescriptions every 5 minutes, which is also a red flag for suspicious behavior), and insurance rejects many of the prescriptions they provide for overuse." The pharmacist also reported that she had "heard that [G.H.] has been arrested."

285. By February 22, 2013, Walmart's compliance team, including at least B.N., knew that G.H.'s and R.M.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from June 26, 2013, through June 18, 2014, of approximately 1,981 of G.H.'s controlled-substance prescriptions. They chose to act and not act in ways that led to the filling, from June 26, 2013, through February 28, 2015, of approximately 7,968 controlled-substance prescriptions written by R.M. These prescriptions included approximately 551 prescriptions filled from October 2013 through December 2014 by Store 8134, the store that sent the September 2013 email described above.

286. As one egregious example of Walmart's unlawful dispensing, in October 2013, a single Walmart pharmacy gave to customer C.S. massive quantities of controlled substances based on prescriptions that G.H. wrote for three different opioids (fentanyl, oxycodone, and methadone), a benzodiazepine, and a muscle relaxant, carisoprodol. The same pharmacy gave C.S. similar quantities of those drugs in December 2013 and in January and February 2014. It

was not until April 2014 that a pharmacist at a different Walmart pharmacy refused to fill C.S.'s prescriptions, noting that the doses "presented significant risk for respiratory depression" and that C.S.'s husband also presented several controlled-substance prescriptions.

287. As another example, a Walmart pharmacy, on a single day each month from October 2013 to February 2014, filled for customer L.M. three opioid prescriptions—each one with over 100 tablets—and a prescription for a muscle relaxant, all from invalid prescriptions that G.H. wrote.

288. In 2014, the Oklahoma State Board of Medical Licensure and Supervision filed complaints against G.H. and R.M. R.M. voluntarily surrendered his medical license in May 2015, admitting that he prescribed controlled substances for other than legitimate purposes or outside the usual course of professional practice.

289. In July 2015, the Oklahoma State Board of Medical Licensure and Supervision revoked G.H.'s license after an evidentiary hearing finding that, among other things, G.H. engaged in the "indiscriminate or excessive prescribing, dispensing or administering of Controlled or Narcotic drugs."

H.D.: "filling for him is a risk that keeps me up at night"; "our concerns are falling upon deaf ears"

290. H.D. was a doctor who ran pain management clinics in Sherman, Paris, and Sulphur Springs, Texas. In 2016, he ranked second in the State of Texas for the number of doses of hydrocodone prescribed and seventh for the number of oxycodone doses.

291. Between 2010 and 2017, seven overdose deaths were connected to prescriptions written by H.D. A medical assistant from H.D.'s Paris, Texas, office recalled that the office would receive calls from individuals expressing concern about their family members misusing their prescriptions. When H.D. was not in the office, he instructed his medical assistant to issue

electronic prescriptions, including prescriptions for Schedule II controlled substances, as if they were being prescribed by H.D. Another medical assistant viewed posts on H.D.'s clinic's Facebook page in which patients discussed selling drugs. Another employee reported that she encountered patients who came to the office and appeared to be "under the influence."

292. H.D.'s prescribing practices and his patients raised numerous red flags identified in Walmart's own policies and by DEA, including, among others, questionable drug combinations, excessive quantities of controlled substances, cash-paying patients, and requests for early refills.

293. On February 10, 2014, a Walmart employee emailed a Market Health and Wellness Director stating that another pharmacy, and possibly [another national retail pharmacy] as well, were "refusing all prescriptions" from H.D. The same day, the email was forwarded to D.M., a senior director on the compliance team. The Market Health and Wellness Director stated that the pharmacist brought up "a good point" and asked, "If our competitors will not fill for them, should we stop as well?" D.M. responded that Walmart leaves decisions about dispensing to the pharmacists' "professional judgment" and that Walmart continued "to look at new ideas."

294. On November 23, 2014, an assistant pharmacy manager at Store 975 in Durant, Oklahoma, emailed a fellow Walmart employee, explaining that "the corporate offices of [two national retail pharmacies] have told their pharmacists that they are not allowed to fill [controlled substances] from [H.D.] at all period." The assistant manager stated, regarding [one of those competing pharmacies], that its "corporate offices sent out a letter saying that they weren't to fill for him due to some legal issues being investigated with his practice and prescribing and they didn't want their pharmacists 'put at risk' filling these medications that were not needed and

overdosing of his patients."

295. Despite these reports from Walmart pharmacists about H.D.'s egregious prescribing patterns, the compliance team prohibited those pharmacists from refusing to fill H.D.'s prescriptions as a blanket matter. On December 23, 2014, a pharmacy manager at Store 147 emailed Walmart's compliance team and explained that H.D. was "under investigation by the DEA" and that "Walmart is getting slammed with [Schedule II controlled substances] and other control [sic] substances from" him. And the issue was not just the volume of H.D.'s controlled-substance prescriptions but also that he prescribed opioids after "'videochats'," sent prescriptions via FedEx for people living more than 100 miles away, and had "'patients'" (quotations in original) who arrived three at a time with prescriptions for methadone, Norco (brand name of hydrocodone-acetaminophen), Xanax (brand name of alprazolam), and MS Contin (brand name of extended-release morphine). The pharmacy manager further explained that four competing pharmacies, including three national chain pharmacies, would not honor prescriptions from H.D. B.N. responded the next day, explaining, in part, that "[b]eing under investigation is simply a red flag to consider when using your professional judgment" and that "an investigation of itself is not a good reason to discontinue filling legitimate prescriptions." B.N. stated, "Remember we are not allowed to blanket refuse to fill for any prescriber." In response, another Walmart pharmacist emailed, stating that while she preferred "to go through the proper channels in situations like this, . . . it seems as if our concerns are falling upon deaf ears." She warned, "This situation is serious and I am considering contacting the Medical Board/DEA/DPS on my own."

296. Reports about H.D.'s pill-mill practices continued in 2015. On February 6, 2015, senior director D.M. received an email from a Walmart pharmacy manager in Sherman, Texas,

explaining the concern that H.D. "may be a pill mill." The email identified red flags about H.D.'s prescribing practices, including that he booked patients 10 minutes apart, most patients paid with cash, and he refused to answer calls from the pharmacy with questions about prescriptions.

297. The same day, the pharmacy manager from Store 147 in Denison, Texas, who had asked for help in December 2014, sent an email to Walmart's compliance team, including B.N., about H.D.—copying employees from other Walmart pharmacies—explaining that the situation "has gotten worse," that she and other pharmacists "are all concerned about our jobs and about filling for a pill mill doctor," that her understanding was that other chain pharmacies were refusing to fill prescriptions issued by H.D., and that "I am in my 29th year with [W]almart and have never had a situation this bad with a doctor." They received so many of H.D.'s prescriptions that if they completed a form each time they refused to fill a prescription, "that is all we would do all day long[.]"

298. In a different email on February 6, 2015, another Walmart employee at Store 147 commented that at least some of H.D.'s prescriptions were not legal and that "[f]illing for him is a risk that keeps me up at night."

299. By February 10, 2014, Walmart's compliance team, including at least B.N. and D.M., knew that H.D.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. For years, until the team corporately blocked H.D. on March 2, 2017, they chose to act and not act in ways that led to the filling, from February 10, 2014, through May 12, 2017, of approximately 12,573 of H.D.'s invalid prescriptions (an average of more than 10 such prescriptions per day), amounting to approximately 1,372,839 dosage units. Among many others, Walmart filled the following

prescriptions written by H.D. during this period:

- Approximately 4,873 hydrocodone prescriptions;
- Approximately 1,179 alprazolam prescriptions;
- Approximately 1,219 oxycodone prescriptions;
- Approximately 834 morphine prescriptions; and
- Approximately 551 fentanyl prescriptions.

300. From 2011 through 2017, approximately 168 different Walmart pharmacies filled controlled-substance prescriptions written by H.D. H.D.'s practice remained in Texas during this period, while these Walmart pharmacies were located in approximately 134 different towns or cities across 18 different states.

301. Walmart filled multiple invalid prescriptions written by H.D. that the Texas Medical Board later used as evidence that H.D. had engaged in non-therapeutic prescribing and overprescribing of opioids and violated a physician's standard of care.

302. As alleged above, on July 6, 2017, a federal grand jury indicted H.D. for CSA violations and other federal crimes. H.D. was later convicted and sentenced to 20 years in prison.

J.F.: Prescriber of very heavy doses

303. J.F. was an internal medicine doctor in Silver City, New Mexico. His practice exhibited numerous signs of a pill-mill operation. J.F. prescribed large dosages of opioids to 680 patients in 2015 alone; prescribed controlled substances to patients from nine states outside New Mexico; prescribed the trinity combination of an opioid, a benzodiazepine, and carisoprodol; and ignored evidence that his patients were abusing and/or diverting controlled substances. Medical records for many of his patients were incomplete or appeared to be templates, and, in many

instances, the patient files did not include any records to corroborate the diagnoses of chronic pain conditions for which J.F. prescribed controlled substances.

304. On multiple occasions, Walmart pharmacists reported to the compliance team that J.F. refused to respond to their questions or concerns related to his patients' prescriptions. In November 2013, a pharmacist refused to fill a prescription for hydromorphone 8mg and wrote in the refusal-to-fill form that "[p]rescriber will not return calls." In June 2015, another Walmart pharmacist contacted J.F. about a patient who was attempting to fill a prescription too soon but J.F.'s office "did not reply as to cancel the prescription or any other info." Also in June 2015, the pharmacist who complained nearly a year and a half earlier that J.F. would not return calls reported that he was experiencing the same problem. In this instance, the pharmacist told an employee at J.F.'s office that he was not comfortable filling a hydrocodone prescription because the patient was already taking Soma, a controlled-substance muscle relaxant, and a benzodiazepine. J.F., again, did not call the pharmacist back and the pharmacist refused to fill the prescription.

305. Walmart pharmacists also saw that J.F.'s patients engaged in pharmacy and doctor shopping. As early as December 10, 2013, a pharmacist at Store 1357 in Silver City, New Mexico, refused to fill one of J.F.'s prescriptions because, as the pharmacist reported to the compliance team in a refusal-to-fill form, the patient was "traveling from Las Cruces to see a Dr in Silver City" and the "PMP shows [the patient] is getting narcotics from multiple doctors and filling at multiple pharmacies." Nine days later, the pharmacist refused to fill another prescription for one of J.F.'s other patients because, as the pharmacist reported in a refusal-to-fill form, the "PMP showed [the patient] filling at multiple pharmacies and by multiple doctors" and "[u]pon questioning [the patient] revealed he lives in Arizona." The pharmacist submitted

additional refusal-to-fill forms for J.F.'s prescriptions in 2014 and 2015 that reported more instances of pharmacy and doctor shopping by J.F.'s patients.

306. At least six Walmart pharmacists from four pharmacies in New Mexico submitted refusal-to-fill forms between November 2013 and April 2016 reporting their inability to resolve red flags raised by J.F.'s prescriptions, including that his patients sought early refills, were pharmacy and doctor shoppers, and were suspected of using the drugs for other than legitimate medical purposes.

307. On August 16, 2014, a pharmacist in Las Cruces, New Mexico, refused to fill an oxycodone 15mg prescription written by J.F., explaining that the "doctor . . . out of silver city is prescribing alot [sic] of narcotics to known people who have substance abuse problems."

308. J.F.'s patients pharmacy shopped among different Walmart pharmacies. For example, on June 3, 2014, A.S. visited Walmart Store 1357 in Silver City, New Mexico, and presented a prescription that J.F. had written for oxycodone 15mg, but the prescription was refused. After Store 1357's refusal, two other Walmart pharmacies filled A.S.'s oxycodone 15mg prescriptions, and one of those pharmacies also filled A.S.'s morphine sulfate ER 30mg prescription.

309. By December 10, 2013, Walmart's compliance team, including at least B.N., knew that J.F.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from December 10, 2013, through May 26, 2016, of approximately 13,458 of J.F.'s invalid controlled-substance prescriptions, including approximately 457 paid for in cash and approximately 240 involving patients from states different from that of J.F. and/or the pharmacy.

310. In at least one case, Walmart's dispensing of J.F.'s invalid prescriptions had

deadly consequences. On January 29, 2015, Walmart filled three prescriptions written by J.F. for S.B., who was 34 years old at the time: oxycodone 15mg (120 tablets), morphine sulfate ER 30mg (90 tablets), and alprazolam 1mg (90 tablets). Two days later, S.B. died from the toxic effects of multiple drugs, including oxycodone, alprazolam, and morphine. A medical expert retained by the New Mexico Medical Board opined that J.F. prescribed this "dangerous drug cocktail" without a legitimate medical purpose.

311. In May 2016, the New Mexico Medical Board summarily suspended J.F.'s license after its investigation revealed egregious conduct reflecting an abandonment of the legitimate practice of medicine. To resolve this action, J.F. voluntarily surrendered his medical license in May 2017. Walmart's compliance team did not corporately block J.F. until January 19, 2018.

J.I.: A "known pill-mill doctor"

312. J.I. was a pain management doctor who practiced at her own clinic in Clearwater, Florida. J.I. would write prescriptions for patients whom she did not meet or examine and who did not even come to her office. Instead, patients' family members and/or friends would go to J.I.'s office to pick up prescriptions written by J.I. in the patients' names for large quantities of controlled substances. Patient records were largely identical for each visit and did not reflect the individualized analysis that would be expected from visit to visit. J.I. also had patients who traveled long distances to her clinic from cities in Florida, including Port Saint Lucie (202 miles), Tamarac (263 miles), Ft. Lauderdale (270 miles), and Graceville (383 miles).

313. In 2006, DEA had revoked J.I.'s registration after she prescribed controlled substances to three undercover law enforcement officers who had admitted to her that they actually were not suffering from any pain. Her registration later was restored, but she was required for a period of one year to provide DEA with monthly reports about her controlled-substance prescriptions. In three separate administrative complaints filed in 2013, the Florida

Department of Health alleged that J.I. prescribed excessive and/or inappropriate amounts of opioids without adequate justification.

314. From June 2012 through July 2015, Walmart's compliance team received more than 100 refusal-to-fill forms about J.I. and learned that J.I. prescribed opioids in excessive amounts and in dangerous combinations with other opioids, amphetamines, benzodiazepines, and muscle relaxers.

315. Refusal-to-fill forms submitted in 2014 repeatedly warned Walmart's compliance team about J.I.'s pill-mill practices. For example, a pharmacist at Store 1712 in Largo, Florida, reported in a refusal-to-fill form dated April 2, 2014, that J.I. was a "known pill-mill doctor" and then reported in August 2014 that she was a "MILL PILL DR [sic]." Another pharmacist at Store 4667 in Clearwater, Florida, reported in refusal-to-fill forms on January 14, 2014, on May 6, 2014, and again on August 10, 2014, that J.I. "routinely writes for larg[e] doses of controlled substance."

316. Walmart pharmacists also alerted Walmart's compliance team that J.I. had a public history of actions taken against her by regulatory authorities based on improper controlled-substance prescribing. On July 5, 2013, a Walmart pharmacist in Florida refused to fill a prescription issued by J.I. because he was "not comfortable with the dose of the medication or the prescriber due to previous issues with DEA." On April 15, 2014, a Walmart pharmacist at a different store in Florida refused to fill a prescription issued by J.I., describing her as a "very questionable doctor who has been investigated and suspended previously." And in July 2015, a Walmart pharmacist reported that there were "3 complaints under prescriber's license for CII [Schedule II controlled substances] prescribing."

317. Some of J.I.'s patients whose prescriptions were refused at one Walmart

pharmacy simply shopped their prescriptions to other Walmart pharmacies or later returned to the pharmacy that refused to fill their prescription. For example, on July 10, 2014, a Walmart pharmacist at Store 2081 in Clearwater, Florida, refused to fill a prescription for methadone 10mg for patient J.C., noting that J.I. was a "doctor known to be heavy prescriber of C-IIs [Schedule II controlled substances]." Twelve days later, Store 2796 in Oldsmar, Florida, filled for J.C. five controlled-substance prescriptions written by J.I., including morphine sulfate ER 100mg and hydrocodone-acetaminophen 10/325mg. Then, on August 2, 2014, Store 2081—the pharmacy that had refused to fill J.C.'s methadone prescription less than a month earlier—filled J.C.'s methadone 10mg prescription. After August 2, 2014, Walmart pharmacies filled more than 160 prescriptions for J.C. that J.I. had written.

318. As another example, on October 10, 2014, a Walmart pharmacist at Store 2796 in Oldsmar, Florida, refused to fill a prescription for methadone 10mg written by J.I. for patient B.S., noting "other customers coming from this doctor's facility with questionable prescriptions." Three days later, B.S. returned to Store 2796 and the pharmacy filled B.S.'s prescription for methadone 10mg (203 tablets), and, nine days after that, Store 2796 gave B.S. 337 more tablets of methadone 10mg. After October 22, 2014, Walmart filled more than 36 opioid prescriptions for B.S. written by J.I.

319. By July 5, 2013, Walmart's compliance team, including at least B.N., knew that J.I.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. Until the team corporately blocked J.I. on March 16, 2017, they chose to act and not act in ways that led to the filling, from July 5, 2013, through March 15, 2017, of approximately 7,958 of J.I.'s invalid controlled-substance prescriptions, including approximately 973 that were paid for in cash.

320. J.I. pled guilty in September 2018 to federal healthcare fraud charges, admitting that she wrote prescriptions, including prescriptions for controlled substances, in the name of certain individuals but then gave the prescriptions to their family members, never having seen or examined the individuals J.I. knew would be the ultimate users of the drugs. She was sentenced to six months of imprisonment and permanently surrendered her medical license and DEA registration.

M.L.: "continually writes for high quantities of narcotics"

321. M.L., a nurse practitioner, owned and worked at a pain clinic in Colorado Springs, Colorado. M.L. was a prescriber primarily to United States military personnel in the TRICARE network. He was known for prescribing the trinity combination of an opioid, a benzodiazepine, and a muscle relaxant. In 2012, M.L. was the nation's number-seven prescriber of the trinity combination. One former patient, a military veteran, described M.L. as a "pill pusher" and "upscale dope dealer."

322. M.L. received a January 2013 admonition by the Colorado State Board of Nursing for prescribing "excessive" dosages of OxyContin that were inconsistent with the patient's underlying condition. The letter became a permanent and public portion of M.L.'s record.

323. In September 2013, a Walmart pharmacist at Store 3582 in Colorado Springs reported to Walmart's compliance team M.L.'s inappropriate prescribing. The pharmacist submitted a refusal-to-fill form explaining that M.L. "continually writes for high quantities of narcotics." The rejected prescription was for a huge amount: 600 tablets of oxycodone 30mg, providing up to 20 tablets per day, which exceeded a daily limit set by Walmart as a computerized "edit" that alerted pharmacists when a certain threshold was exceeded.

324. Walmart pharmacists repeatedly reported that, when M.L. was contacted about problematic prescriptions, he failed to justify the prescriptions. In some cases, after one Walmart

pharmacist refused to fill a prescription that M.L. had written, the customer would simply fill it at another Walmart pharmacy.

325. For example, on March 6, 2015, a Walmart pharmacist at Store 3582 in Colorado Springs refused to fill an oxycodone 30mg prescription after speaking with someone in M.L.'s office who was able to provide only "nonspecific" answers to questions about the existence of a treatment plan or the consideration of treatment options for the patient. Just three days later, on March 9, 2015, a nearby Walmart pharmacy at Store 4335 in Falcon, Colorado, dispensed 360 tablets of oxycodone 30mg for the same customer based on a prescription from M.L.

326. As another example, in May 2015, a Walmart pharmacist at Store 3582 in Colorado Springs spoke with M.L. by telephone, informing him that three Walmart pharmacists were uncomfortable filling patient G.J.'s prescription due to the high quantity of oxycodone 30mg (15 tablets per day). M.L. failed to offer any justification but responded simply with "ok." By May 2015, Walmart already had filled five oxycodone 30mg prescriptions for G.J., and each prescription was for a very large amount of oxycodone, from 300 to 360 tablets. Days after Store 3582 refused to fill G.J.'s prescription, G.J. visited Store 5123, also in Colorado Springs, and filled his oxycodone 30mg prescription written by M.L. Later that month, G.J. visited a third Walmart pharmacy in Colorado Springs, Store 1896, and filled prescriptions from M.L. for clonazepam 0.5mg, Oxycontin ER 80mg, and methylphenidate 5mg (brand name Ritalin).

327. On September 20, 2013, Walmart's compliance team, including at least B.N., knew that M.L.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from September 20, 2013, through March 30, 2016, of approximately 4,503 of M.L.'s invalid controlled-substance prescriptions.

328. Walmart filled over 100 of those invalid controlled-substance prescriptions for customer A.D. A.D. first saw M.L. in 2011, when she was 25 years old, for pain following a motorcycle accident. M.L. prescribed opioids to A.D. on the initial visit and never attempted to decrease the amount of opioids he prescribed. Eventually, A.D. became addicted to the opioids that M.L. prescribed. A.D. continued seeing M.L. until he closed his practice. A.D. then began using heroin. A.D.'s addiction ruined many years of her life. In 2019, A.D. weaned herself off all opioids.

329. Walmart filled A.D.'s first opioid prescription from M.L. and continued filling her prescriptions until February 2016. From January 2013 until February 2016, Walmart dispensed massive quantities of opioids to A.D., in addition to benzodiazepines. For example, on August 11, 2013, Walmart dispensed to A.D. oxycodone 30mg (165 tablets), methadone 10mg (90 tablets), and alprazolam 2mg (90 tablets). The average daily morphine milligram equivalent for A.D.'s methadone and oxycodone prescriptions that month was 615. Just 15 days later, on August 26, 2013, Walmart gave A.D. another 165 tablets of oxycodone 30mg. The following month, Walmart gave A.D. 330 tablets of oxycodone 30mg, 90 tablets of methadone 10mg, and 90 tablets of alprazolam 2mg. On a monthly basis until February 2016, Walmart gave A.D. large quantities of opioids (eventually including fentanyl) and benzodiazepines.

330. According to A.D., Walmart pharmacists never asked her any questions about her prescriptions, and she did not recall Walmart contacting M.L. to discuss her prescriptions. Walmart never refused to fill any of her prescriptions.

331. Walmart also filled more than 140 invalid prescriptions for customer M.H. M.H. began seeing M.L. in 2011 for back pain. M.L. prescribed opioids, benzodiazepines, and muscle relaxants to M.H., and he would prescribe her different opioids when she told him she did not

like what she was taking. M.H. became addicted to the opioids prescribed by M.L. and described her life as being terrible during that time. M.H. eventually quit taking opioids.

332. Walmart dispensed to M.H. large quantities of opioids, benzodiazepines, and sedatives from at least January 2013 through March 2016. For example, during a four-day period from May 15, 2014, until May 19, 2014, Walmart gave M.J. 120 tablets of oxycodone 20mg, 240 tablets of oxycodone-acetaminophen 10/325mg, 90 tablets of diazepam 10mg, 90 tablets of alprazolam 2mg, and 30 tablets of zolpidem 10mg. The following month, from June 14, 2014, until June 23, 2014, Walmart gave M.H. even more opioids, plus benzodiazepines and a sedative—120 tablets of oxycodone 20mg, 240 tablets of oxycodone-acetaminophen 10-325mg, 180 tablets of morphine sulfate 30mg, 90 tablets of alprazolam 2mg, 90 tablets of diazepam 10mg, and 30 tablets of zolpidem 10mg. These dispensing patterns continued for months.

333. M.H. paid for her prescriptions in cash, and Walmart never refused to fill any of her prescriptions. M.H. also does not recall any Walmart pharmacists calling M.L.'s office to ask questions about her prescriptions.

334. In January 2017, M.L. surrendered his nursing license and prescribing authority to settle a disciplinary action. He admitted that his treatment plans for 12 patients were "inappropriate" and that he had continued opioid therapy in cases where the patient was not benefiting and despite a patient's violation of an opioid agreement. He also admitted that his documentation was "substandard," in part because it failed to explain his increases in opioid therapy.

M.M.: A "known pill mill" who sent his patients to Walmart

335. M.M. was a doctor in Orlando, Florida, whose medical practice had all the features of a classic pill-mill operation. He falsified medical records to justify prescriptions for

dangerously excessive amounts of controlled substances, permitted his patients to choose their opioid medications during their brief encounters with him, and prescribed medications that he knew would be diverted. He prescribed the trinity combination frequently and in large doses.

336. M.M. was arrested in June 2010 in "Operation Pain Killer," as reported in the local press, and charged with illegal trafficking of hydrocodone. He pleaded *nolo contendere* (no contest) in February 2013 to an amended charge of racketeering and was sentenced to 15 years' probation.

337. In October 2011, Florida's Department of Health filed multiple administrative complaints against M.M., and it filed an amended complaint in April 2013, all related to his illegal prescribing habits under the guise of practicing medicine. The allegations included that he prescribed excessive amounts of the trinity combination, prescribed controlled substances without following standard practices such as regular urine screens, and prescribed combinations and quantities without medical justification. He also allegedly let a patient choose her own drugs, wrote prescriptions knowing the patient's intent to distribute the drugs, and lied in a patient's medical records to falsely state that a patient suffered from pain.

338. Because the Florida Department of Health records were public, Walmart's compliance team learned about the Department's complaints in September 2012. That month, a Walmart pharmacist at Store 943 in Winter Park, Florida, discovered the Department of Health complaints and reported in a refusal-to-fill form on September 24, 2012, that M.M. had "several complaints" on file with the "dept of health."

339. Just a few weeks after M.M.'s plea, Walmart's compliance team became aware of M.M.'s criminal conviction. On February 23, 2013, a pharmacist at Store 5106 in Oviedo, Florida, reported, in a refusal-to-fill form, M.M.'s arrest and plea to racketeering and said that he

was "not comfortable with prescriber." The pharmacist also reported that he had rejected an oxycodone-acetaminophen prescription written by M.M. This refusal was included in a spreadsheet summary that was sent to B.N. in April 2013. A Senior Director of Quality Improvement and Clinical Services was copied on the email and suggested in May 2013 to G.C. that they discuss the list of refusals. Other Walmart pharmacists also reported M.M.'s criminal charges in refusal-to-fill forms and described him as suspicious. In October 2015, a field manager described M.M. as a "known pill mill" and cited the case number of one of five Florida Department of Health complaints filed against the doctor. The manager was concerned that a particular store had filled M.M.'s prescriptions and that the store showed other concerning dispensing patterns. He believed that "this is something that should be looked into before the DEA comes knocking on our door." M.J., in an email discussion that included B.N. and C.R., did ask for an analysis of the store's dispensing, and dispensing for M.M. in particular. That analysis noted that there were 159 refusal-to-fill forms submitted for M.M.'s prescriptions.

340. M.M.'s prescribing habits were so clearly invalid that, as Walmart pharmacists were told, non-Walmart pharmacies had stopped filling his prescriptions. On January 22, 2016, a pharmacist at Store 2881 in Kissimmee, Florida, reported in a refusal-to-fill form that a patient had asked the pharmacist where he could go to fill the prescription. The patient said that M.M. had instructed him not to take his prescription to [four competing retail pharmacies] but said that "[another pharmacy chain] and Walmart were ok."

341. The above-described reports are just a small sample of the egregious red flags reported by Walmart pharmacists, who repeatedly told the compliance team that M.M. wrote prescriptions for illegitimate purposes, without a valid doctor-patient relationship, and for inappropriate therapies and excessive quantities. The pharmacists also reported other red flags

related to his patients, who were doctor and pharmacy shoppers, paid in cash, sought early refills, or appeared intoxicated.

342. In some instances, after one Walmart pharmacist refused to fill a prescription issued by M.M., another Walmart pharmacist would fill that prescription or a similar one for the same customer. For example, on September 3, 2015, Walmart Store 5106 in Oviedo, Florida, refused to fill customer J.A.'s prescriptions for Adderall 30mg and alprazolam 2mg because M.M. "was arrested and pleaded no contest to racketeering. He is presently on 15 years probation." Later the same day, a different Walmart pharmacy, Store 1084 in Orlando, Florida, filled J.A.'s prescription for alprazolam 2mg, and, six days after that, yet another Walmart pharmacy in Orlando, Store 4142, filled J.A.'s prescription for Adderall 30mg. On eight occasions in the next five months, Walmart pharmacies in Orlando filled J.A.'s prescriptions for alprazolam 2mg, Adderall 30mg, or both.

343. By February 23, 2013, Walmart's compliance team, including at least B.N., knew that M.M.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from June 26, 2013, through August 15, 2016, of approximately 8,021 of M.M.'s invalid controlled-substance prescriptions, including approximately 1,349 that were paid for in cash.

344. M.M. ultimately declined to contest the allegations in the three administrative complaints against him, leading to his voluntary relinquishment of his medical license, effective April 2016.

M.N.-A.: "many DEA red flags present"

345. M.N.-A. was a neurologist in Charleston, West Virginia, who flooded his community with opioids. From January 2013 through March 19, 2018, M.N.-A. wrote prescriptions totaling more than seven million dosage units. More than 60 percent of those

prescriptions were for Schedule II controlled substances, and less than two percent of the prescriptions were for non-scheduled drugs. The top-10 drugs he prescribed were all opioids. The most common drug he prescribed was hydrocodone-acetaminophen 10/325mg, and the second-most common was oxycodone 30mg.

346. M.N.-A.'s practice bore many other signs of being a pill mill. His patients' medical records were often cut-and-paste from one visit to another and contained no medical justification for the large quantities of Schedule II controlled substances he prescribed. Additionally, appointments were very short. According to employees of M.N.-A.'s practice, he typically saw 80 to 90 patients per day, and each follow-up appointment lasted for just a few minutes. Employees also recalled receiving multiple calls a day from his patients' family members expressing concern about M.N.-A.'s treatment. Employees observed patients in the waiting room who appeared intoxicated, with one employee recalling an instance where a patient fell asleep on the toilet while giving a urine sample.

347. Certain Walmart pharmacists recognized red flags associated with M.N.-A.'s practice and reported those red flags to the compliance team. In two refusal-to-fill forms submitted in July 2015, Walmart pharmacists reported that non-Walmart pharmacies near Walmart Store 2036 in South Charleston, West Virginia, had stopped filling M.N.-A.'s prescriptions.

348. One of those refusal-to-fill forms, submitted on July 8, 2015, also reported many other red flags raised by M.N.-A.'s prescriptions: "There were many DEA red flags present which led us to turning the script away such as patient traveling a long distance to the pharmacy, duplication of prescribing habits from physician, patient trying to force the pharmacy to fill the prescription and acting in an [un]usual manner." One customer told the Walmart pharmacist that

three other pharmacies would not fill her prescription. A pharmacist from one of those pharmacies also spoke directly with a Walmart pharmacist at the South Charleston store and reported that the pharmacy had stopped filling for M.N.-A.

349. Some of M.N.-A.'s patients shopped their prescriptions around to different Walmart pharmacies. For example, in July 2015, a pharmacist at Store 2036 refused to fill a prescription written by M.N.-A. for Norco 10/325mg (brand name for hydrocodone-acetaminophen 10/325mg) for patient V.C. The following month, and every month thereafter through May 2016, a different Walmart pharmacy in South Charleston, Store 6457, filled V.C.'s prescriptions for hydrocodone-acetaminophen 10/325mg.

350. As another example, in April and June 2015, the pharmacy at Walmart Store 2036 filled N.T.'s prescriptions for hydrocodone-acetaminophen 5/325mg that M.N.-A. wrote. Then, on August 5, 2015, the same pharmacy refused to fill N.T.'s hydrocodone-acetaminophen prescription, choosing numerous unresolved red flags related to M.N.-A. and the patient from the list of options in Archer: writes a large number or percentage of controlled substances; writes same medication, dosage, directions for large number of individuals; routinely writes for large doses of controlled substances; provides the same diagnosis for majority of individuals; evidence of "pharmacy shopping"; and patient resides outside of trade area of pharmacy. After Store 2036 refused N.T.'s hydrocodone-acetaminophen prescription, N.T. took that prescription the following month to Store 2610 in Logan, West Virginia, about an hour from Charleston. Store 2610 filled two hydrocodone-acetaminophen prescriptions for N.T. Then, in January 2016, N.T. returned to Store 2036. Despite its previous refusal, Store 2036 now filled an even higher dosage: hydrocodone-acetaminophen 10/325mg. Store 2036 continued to fill N.T.'s prescriptions for hydrocodone-acetaminophen until mid-2016.

351. Walmart Store 2036's willingness to fill M.N.-A.'s prescriptions did not go unnoticed. One of M.N.-A.'s former employees who worked at his office in 2015 observed that office staff told patients where to fill M.N.-A.'s prescriptions, usually instructing them to go to Walmart Store 2036.

352. In February 2017, a Walmart pharmacist at Store 4278 in Quincy, West Virginia, reported to Walmart's compliance team, including M.J., that she had decided that all of M.N.-A.'s prescriptions should be refused.

353. By July 8, 2015, Walmart's compliance team, including at least M.J., knew that M.N.-A.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. Until the team corporately blocked M.N.-A. on March 9, 2018, they chose to act and not act in ways that led to the filling, from July 8, 2015, through July 27, 2018, of approximately 2,853 of M.N.-A.'s invalid controlled-substance prescriptions.

354. In July 2018, M.N.-A. was indicted on federal drug trafficking charges. M.N.-A. pled guilty to knowingly and intentionally distributing methadone not for a legitimate medical purpose in the usual course of professional practice. Walmart dispensed the invalid methadone prescription that was the subject of M.N.-A.'s guilty plea. M.N.-A. was sentenced to more than five years in prison.

P.T.: The "Candy Man"; "too many questions regarding the ethics and integrity of this physician"

355. P.T. was an internal medicine doctor practicing in Milford, Delaware. Although P.T. was not trained or certified in pain management, 75 to 80 percent of P.T.'s patients came to him for pain management. Roughly half of his patients paid in cash.

356. P.T. was well known in Delaware for overprescribing opioid medications. Two former employees of P.T.'s practice said that people would frequently refer to P.T. as "Candy

Man" because of the number of opioid pills he prescribed. A pharmacist at a non-Walmart pharmacy in Milford, Delaware, reported that, immediately after opening in 2013, they began to receive a deluge of prescriptions from P.T. He described P.T. as operating the "Disneyland for opiates" and concluded, based on his corresponding responsibility as a pharmacist, that he should not fill any prescriptions from P.T. An emergency room doctor told investigators that the emergency room would see five to 10 patients a night experiencing opioid withdrawal and that these were largely patients who had been seen by P.T.

357. In 2013, pharmacists at Walmart Store 1741 in Milford observed that P.T.'s patients traveled long distances to get pain medications from him. For example, on November 26, 2013, a pharmacist refused to fill prescriptions for oxycodone and methadone based on unresolved red flags, explaining, "Patient from out of state – never a patient here – Dr. [P.T.] RX-he is not a pain mgmt specialist – Patient unable to give valid reason for needing Rx's." The same day, another pharmacist at Store 1741 refused to fill a prescription for Percocet 7.5/325mg, citing unresolved red flags: "Pt is from MD, travel 45 mins to see Dr [P.T.] and was unable to provide a valid reason why she has to come to DE." Just a few days later, the same pharmacist refused to fill an oxycodone 15mg prescription, citing more unresolved red flags: "Pt is from maryland and have a dr in md but comes to de to see dr [P.T.] for narcotic medicines. Was not able to give me a valid reason why his other primary care dr can not take care of his pain medicine."

358. On January 10, 2014, the pharmacy manager from Store 1741 in Milford, Delaware, emailed her Market Health and Wellness Director about P.T. The manager reported that she had spoken with the manager of Delaware's prescription monitoring program and learned "interesting information" about P.T. that "needs to be forward[ed] to all pharmacist[s]

and our compliance and ethical Department." The manager told the director that two large chain pharmacies and a local pharmacy were no longer filling P.T.'s prescriptions. She added that, although P.T. claimed to be a pain management doctor, "according to the board of pharmacy he is not." The manager of the prescription monitoring program had told the pharmacy manager that Walmart was filling more of P.T.'s prescriptions because other pharmacies were refusing them. The pharmacy manager said that she thought Walmart needed "to do something at [the] corporate level."

359. The pharmacy manager's email was forwarded to Walmart's compliance team. On January 15, 2014, C.R. wrote back with the boilerplate POM 1311 response: "Pharmacists are granted the ability to exercise their professional judgment and choose to refuse to fill any prescription if they feel the prescription was written for other than a legitimate medical purpose," but "no blanket refusals are allowed by the Boards of Pharmacy."

360. Predictably, after the pharmacy manager asked Walmart's compliance team "to do something at [the] corporate level" about P.T. and the compliance team told her she was not allowed to blanket refuse to fill P.T.'s prescriptions, Store 1741 continued to fill prescriptions issued by P.T. Specifically, after January 15, 2014, Store 1741 filled approximately 145 controlled-substance prescriptions issued by P.T..

361. Also in January 2014, another Walmart pharmacy in Delaware reported to the compliance team its concerns about P.T. On January 21, 2014, a pharmacist from Store 2791 in Georgetown, Delaware, reported in refusal-to-fill forms that she refused to fill oxycodone 15mg prescriptions from four different P.T. patients. In each instance, she reported, "I have questions about the ethics and integrity of this physician as well as his doctor patient relationships and prescribing for a legitimate health need."

362. P.T.'s patients continued to arrive at Store 2791, and the same pharmacist refused to fill on numerous other occasions. In February 2014, she expanded her explanation for refusing to fill one of P.T.'s prescriptions, reporting, "I have too many questions regarding the ethics and integrity of this physician. I have concerns about his doctor patient relationships as well as prescribing for a legitimate health need. Red Flags: not pain management and most Rx written for oxycodone 15 mg and methadone 10 mg for same qt and sig. Also, Rx did not have quantity spelled out as required by law. I let the patient know this as he may have problems filling elsewhere."

363. By January 15, 2014, Walmart's compliance team, including at least B.N., knew that P.T.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from January 15, 2014, through December 11, 2014, of approximately 1,065 of P.T.'s invalid controlled-substance prescriptions.

364. On July 21, 2021, after a two-week jury trial, P.T. was found guilty of unlawful distribution and dispensing of controlled substances with respect to specific prescriptions he had written to 13 patients, as well as one count of maintaining drug-involved premises. On March 1, 2022, P.T. was sentenced to 20 years in prison.

365. Walmart pharmacies had filled three of the specific prescriptions for which P.T. was convicted. Of the 13 patients whose prescriptions formed the basis of P.T.'s conviction, eight had filled other prescriptions from P.T. at Walmart stores for the same drugs.

366. One of the 13 patients whose prescriptions written by P.T. were the basis of P.T.'s conviction for unlawfully distributing and dispensing oxycodone was D.M. D.M. had presented prescriptions from P.T. at two different Walmart stores on December 3, 2013, and February 11,

2014, that were refused based on unresolved red flags. Notwithstanding those refusals to fill, pharmacists at three other Walmart stores continued to fill prescriptions for D.M. until April 8, 2014.

R.K.: Filling prescriptions from this "pill mill" was "putting pharmacists and Walmart in a bad situation legally"

367. R.K. was a doctor of osteopathic medicine who operated a family medicine practice in Mt. Carmel and Shamokin, Pennsylvania. In 2014, 2015, and 2016, he was the top prescriber of opioids in the Commonwealth of Pennsylvania. From January 2014 to July 31, 2017, R.K. prescribed approximately 9.5 million units of oxycodone, hydrocodone, oxycontin, and fentanyl to his patients.

368. It was common knowledge in Mt. Carmel and Shamokin that patients could easily get narcotics from R.K. As one former patient explained, R.K. was the "go to" for pain pills. Some patients referred to him as "the Maniac" because of the large number of controlled-substance prescriptions he wrote. A police detective from Coal Township, which surrounds Shamokin, reported in mid-2015 that R.K. had prescribed most of the narcotic pills that ended up being sold and used on the streets of the township.

369. Walmart filled thousands of R.K.'s controlled-substance prescriptions. From March 17, 2011, until March 1, 2017, Walmart pharmacies dispensed more than 1.8 million dosage units of controlled substances from 19,915 prescriptions written by R.K.

370. Walmart Store 2481 in Coal Township, Pennsylvania, was situated between R.K.'s Mt. Carmel and Shamokin offices and less than seven miles from each one. Store 2481 dispensed far more controlled-substance prescriptions written by R.K. than any other Walmart pharmacy.

371. In 2013 and 2014, pharmacists at Store 2481 refused to fill certain prescriptions

written by R.K., noting in their refusal-to-fill forms numerous unresolved red flags, including therapeutic duplication, two prescriptions for the same drug for the same individual four days apart, a patient's residence about 60 miles from R.K.'s location, early refills, cash payment, and a large number of controlled-substance prescriptions in a 30-day time period.

372. Despite these red flags, Walmart, and Store 2481 in particular, continued to fill invalid prescriptions written by R.K. For example, after January 1, 2015, Store 2481 filled approximately 152 of R.K.'s controlled-substance prescriptions that were each at least four days early.

373. On May 11, 2015, Store 2481 filled a prescription from R.K. for 120 tablets of oxycodone 5/325mg for customer R.C., but R.C. had died from a drug overdose eight days earlier. R.K. had also prescribed the drugs on which R.C. overdosed.

374. On August 25, 2015, DEA met with the Store 2481 pharmacy manager, F.O., concerning the postmortem fill of R.C.'s prescription. F.O. was unable to retrieve video footage of the individual who had obtained R.C.'s prescription. He did, however, explain that most of the prescriptions that were refused at Store 2481 were issued by R.K. F.O. also said that many patients attempted to refill narcotic prescriptions early and that R.K. wrote many narcotic prescriptions for the same patient just days apart.

375. A few days later, on August 28, 2015, a pharmacist from Store 2481 reported to DEA that it was not uncommon for the pharmacy to sell out of narcotics on the weekends because of the high volume of narcotics that R.K.'s patients were attempting to fill. On Saturday mornings, R.K.'s patients would line up outside the pharmacy before it opened.

376. Although the pharmacists at Store 2481 recognized that R.K. was operating a pill mill, his patients continued filling prescriptions there. On September 23, 2016, a pharmacist at

Store 2481 emailed a Walmart Health and Wellness Director to raise her concerns about R.K., explaining that he "prescribes for oxycodone 30 mg in amounts of 150 [tablets], oxycodone 20 mg 150 [tablets] at a time, oxycodone 10 mg for 360 [tablets], Percocet 5/325 for 240 [tablets] routinely, Percocet 10/325 for 240 [tablets] at a time and norco 5/325 and 10/325 always over 120 [tablets], Xanax 0.5 mg and 1 mg always over 120 [tablets], and adipex and Adderall are usually written together for the same person." Additionally, "[t]hrough the pdmp we find him giving multiple rxs to the same patient for the same drug and they are using different pharmacies." The pharmacist highlighted that "[t]wo pharmacies in town will no longer accept his rxs for narcotics." This email was forwarded up the Walmart corporate chain, including M.J., a director on the compliance team.

377. Despite these unresolved red flags, within the next two weeks, Walmart filled prescriptions for some of the exact drugs, in large quantities, that the Walmart pharmacist had said were concerning but typical for R.K., including 150 tablets of hydrocodone-acetaminophen 10/325mg (brand name Norco) for one individual, 240 tablets of oxycodone-acetaminophen 5/325 (brand name Percocet) for another, and 270 tablets of alprazolam (brand name Xanax) for a third individual.

378. By January 1, 2015, Walmart's compliance team, including at least B.N., knew that R.K.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from January 1, 2015, through February 21, 2018, of approximately 6,430 of R.K.'s invalid controlled-substance prescriptions. Approximately 4,188 of those prescriptions were dispensed by Store 2481 in Coal Township.

379. The compliance team corporately blocked R.K. on March 2, 2017, acknowledging

what they actually knew, or had deliberately ignored, since January 1, 2015, that R.K. was acting outside the usual course of professional practice. And yet, through February 21, 2018, Walmart pharmacies continued to fill prescriptions written by R.K..

380. Ultimately, in December 2017, a federal grand jury indicted R.K. in a 19-count indictment charging, among other things, the unlawful distribution and dispensing of controlled substances, including violations of federal drug laws resulting in the death of five patients. After 13 days of trial, on September 23, 2021, R.K. pled guilty to 12 counts and admitted that the Schedule II narcotic opioid drugs that he prescribed resulted in the deaths of five of his patients. R.K. was sentenced to 15 years of imprisonment.

R.M.: Prescriptions "are likely not prescribed for ethical purposes"

381. R.M. was the sole physician at a pain management clinic in Miami, Florida. His practice exhibited numerous signs of pill-mill activity. For example, it operated on a cash-only basis and did not accept insurance. Numerous "patients" who came to R.M. traveled to his Miami clinic from other states, including large numbers of individuals traveling in groups from southeastern Kentucky—a road trip of approximately 19 hours each way. Many of these individuals were sponsored by drug dealers in Kentucky, who paid for their travel costs in exchange for receiving a portion of the pills that R.M. had prescribed. The waiting room of R.M.'s practice was crowded and, at times, standing-room-only. R.M. would prescribe opioids to patients after spending only a few minutes with them, without performing any type of physical examination, and without requesting or reviewing patients' previous medical or prescription records.

382. Beginning as early as 2012, Walmart pharmacists alerted the compliance team, though refusal-to-fill forms, that R.M.'s prescribing practices were concerning. For example, from December 2012 until September 2014, a Walmart pharmacist at Store 1590 in Hialeah,

Florida, near Miami, reported to Walmart's compliance team that R.M.'s prescriptions were not for a legitimate medical purpose, reflected pattern prescribing, and were "questionable." He wrote prescriptions for high quantities and cocktail combinations and had "multiple patients in short period of time."

383. R.M.'s patients did not attempt to fill his prescriptions only in the Miami area, nor only in Florida. They fanned out across the United States, presenting Walmart pharmacies with red-flag prescriptions in many states. In some cases, Walmart pharmacists refused to fill R.M.'s prescriptions, recognizing that the distances his patients traveled to fill their prescriptions were an unresolved red flag. For example, on June 21, 2013, a Walmart pharmacist in Martin, Tennessee, refused to fill several patients' prescriptions for oxycodone 30mg, noting that the individuals had "landed in Nashville airport on 6/21" and had presented prescriptions at three other Walmart stores, as well as two competing retail pharmacies.

384. In November 2014, a Walmart pharmacist at Store 159 in Columbia, Missouri, refused to fill a prescription written by R.M. because "[p]atient is from Kentucky, doctor from Florida, reason to believe that patient and doctor do not have legitimate relationship." This Walmart pharmacist further noted that this was a pattern with R.M.: "many prescriptions coming through from this doctor from patients who do not live in Florida or in Missouri." The pharmacist recognized the unresolvable red flag with R.M.'s prescriptions, despite that R.M.'s office had represented that the prescriptions were legitimate.

385. On June 24, 2015, a Walmart pharmacist at Store 1828 in Plover, Wisconsin, speaking for herself and a pharmacist at another Walmart pharmacy in Wisconsin, emailed a Market Health and Wellness Director, providing a "list of patients from Kentucky that have been visiting pharmacies in all of central Wisconsin recently." The employee explained that the

patients "are bringing in prescriptions from [R.M.] in Hialeah, FL . . . for Oxycodone 30mg, Percocet, Diazepam and Methadone." The pharmacist concluded, "This is just an alert of our assumptions that these prescriptions *are likely not prescribed for ethical purposes*." (Emphasis added.) The email was shared with at least three Walmart directors on the compliance team.

386. When asked by compliance director C.R. whether he had seen R.M.'s name "on the [refusal to fill]," B.N. responded, "Yep," and commented that "[t]his was the dr we filled rx in [S]alt [L]ake, MISSOURI, Iowa and Arkansas. His patients are famous for the giant triangle for service." (Emphasis in original.)

387. Despite numerous warnings to Walmart's compliance team, many Walmart pharmacies continued to fill R.M.'s prescriptions, including pharmacies in Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin.

388. From July 2014 until October 2015, Walmart pharmacies in Utah dispensed approximately 231 Schedule II controlled-substance prescriptions written by R.M., the majority of which were for oxycodone 30mg, the highest immediate-release strength available.

389. Between December 2013 and July 2015, Walmart pharmacies in Missouri dispensed approximately 63 Schedule II controlled-substance prescriptions written by R.M., again the majority of which were for oxycodone 30mg.

390. From June 2014 through November 2015, Walmart pharmacies in Arkansas dispensed approximately 55 of R.M.'s Schedule II controlled-substance prescriptions, of which 39 were for oxycodone 30mg.

391. Predictably, some of R.M.'s patients, including Y.B. and J.F., engaged in pharmacy shopping among Walmart pharmacies. From November 2014 to January 2015, Y.B. and J.F. filled oxycodone 30mg prescriptions issued by R.M. at three different Walmart pharmacies in Utah. Finally, one of those pharmacies, Store 3589 in Salt Lake City, Utah, refused opioid prescriptions from Y.B. and J.F. on February 9, 2015, writing to the compliance team that "there is something sketchy going on with these out of state oxycodone prescriptions and i did not feel comfortable dispensing, because i was not convinced it was being used for a legitimate medical purpose."

392. The same day, after Store 3589 refused to fill Y.B.'s and J.F.'s prescriptions, Y.B. and J.F. went to Walmart Store 2307 in South Jordan, Utah, which had previously filled for Y.B. Store 2307 filled Y.B.'s and J.F.'s prescriptions and continued to fill them for five more months.

393. By January 2, 2014, Walmart's compliance team, including at least B.N., knew that R.M..'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from January 2, 2014, through May 28, 2016, of approximately 1,280 of R.M.'s invalid controlled-substance prescriptions.

394. In November 2015, a federal grand jury indicted R.M. for violations of federal controlled-substance laws. In December 2019, R.M. pled *nolo contendere* (no contest) to conspiracy to dispense and distribute oxycodone.

R.W.: Prescribed "cocktails" and recommended patients fill at Walmart

395. R.W. was a medical doctor who practiced primarily in McKinney, Texas. During a DEA investigation of R.W., one of his former employees revealed that, for a period of time, R.W. prescribed most of his patients hydrocodone, Xanax, and Soma, which R.W. referred to as the "cocktail," and that "mules" recruited patients from out of town to obtain controlled

substances from R.W., purportedly for illicit use. The investigation revealed that a number of patients sold controlled substances prescribed by R.W. on the street, including one who was later interviewed by DEA and said that she began seeing R.W. after being told he would prescribe anything she wanted.

396. No later than 2014, Walmart pharmacy managers had notified Walmart's compliance team, in emails, of alarming, unresolved red flags about R.W.'s prescriptions. Between February and December 2014, three different pharmacy managers at Store 5311 in McKinney, Texas; Store 4906 in McKinney, Texas; and Store 147 in Denison, Texas, reported to various Walmart compliance team members, including B.N., that R.W.'s prescribing habits had become so concerning that non-Walmart pharmacies in the area had stopped filling his prescriptions and that R.W. was telling his patients to fill their prescriptions at Walmart. Specifically, on February 6, 2014, the pharmacy manager at Store 4906 explained that R.W. was being investigated and other pharmacies in the area had either decided to refuse to fill all of R.W.'s prescriptions or were in the process of so deciding. The pharmacy manager then wrote, "I think we should follow so we are not put in any crazy situation." In March 2014, the pharmacy manager for Store 5311 reported that R.W. was "telling his patients to go to Wal-Mart because they will fill" his prescriptions. And in December 2014, one Walmart pharmacy manager reported that four competing pharmacy chains had implemented corporate blocks on filling R.W.'s prescriptions and that three other competing pharmacy chains and three independent pharmacies would fill a prescription from R.W. only after taking additional steps to verify the validity of a prescription. Through at least July 2016, Walmart pharmacy employees continued to send emails notifying Walmart managers, including members of Walmart's compliance team, of red flags about R.W.'s prescribing habits.

397. Walmart pharmacists reported red flags about R.W. and his patients through refusal-to-fill forms, while other Walmart pharmacists continued to fill his prescriptions. A Walmart pharmacist at Store 947 in Sherman, Texas, reported in a February 2014 refusal-to-fill form that one of R.W.'s patients had attempted to fill a prescription for a drug cocktail 20 days early. The patient claimed that his medication had been stolen in a car accident, but the police, whom the pharmacist had contacted, could not confirm that claim. Another Walmart pharmacist, at Store 5931 in Dallas, Texas, reported in a July 2015 refusal-to-fill form that R.W had "written several prescription[s] for patients on the same drug Hydrocodone 10/325 with a large qty (30 DAYS SUPPLY)." The same Walmart pharmacist at Store 5931 reported later that month that R.W. was "not a pain management [doctor] and not suppose[d] to treat chronic pain."

398. By February 6, 2014, Walmart's compliance team, including at least B.N., knew that R.W.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from February 6, 2014, through November 30, 2016, of approximately 8,606 of R.W.'s invalid controlled-substance prescriptions. Of the approximately 8,606 invalid prescriptions from R.W. that Walmart filled, approximately 725 were paid for in cash. The compliance team corporately blocked R.W. on January 19, 2018.

399. Many of these controlled-substance prescriptions were alarming, as confirmed by a Walmart pharmacy employee who was interviewed by DEA agents in December 2016, when a search warrant was executed at the pharmacy in Store 206 in McKinney, Texas. The employee observed that the number of R.W.'s prescriptions filled by her pharmacy had significantly increased from 2014 to 2016, while competitor pharmacies had stopped filling R.W.'s prescriptions. She stated that she had observed multiple red flags in R.W.'s prescribing habits:

prescriptions for cocktails of drugs that she knew were abused, for high-dose opioids for long periods of time, and for excessive quantities of opioids. She also stated that she believed several of R.W.'s patients did not need the medications for medical purposes, based on their disruptive behavior, including their complaints that they could not get early refills and their demands that they needed their medications "NOW!"

400. A pharmacist who also was interviewed during the same DEA search told DEA agents that, in retrospect, she would not have filled several of R.W.'s prescriptions. She admitted to continuing to fill his prescriptions despite the concerns triggered by the number of the prescriptions he wrote for the same cocktail of drugs, the number of individuals who traveled long distances to get their prescriptions filled at her pharmacy, and the fact that other area pharmacies had stopped filling R.W.'s prescriptions.

401. As just one example of Walmart's unlawful fills, from February 2014 to September 2015, Walmart Store 206 in McKinney, Texas, filled for R.P. prescriptions for hydrocodone and alprazolam (brand name Xanax) that R.W. had written. During this period, in May 2015, R.P. was arrested for selling hydrocodone and Xanax prescribed to her by R.W. and filled at Walmart. In an interview with DEA, R.P. said that she filled her prescriptions at Walmart because it was one of the only pharmacies that would fill R.W.'s prescriptions.

402. In August 2017, R.P. was indicted by a grand jury for illegally conspiring with R.W. to distribute controlled substances. R.W. pled guilty to several counts and was sentenced in February 2018 to 10 years of imprisonment.

S.K.: "there is no way that many 25 year olds need 120 to 240 oxycodone per month"

403. S.K. was a medical doctor who practiced in New Bern, North Carolina. S.K.'s practice exhibited numerous signs of pill-mill activity. For example, S.K.'s business hours

typically began at 4:00 p.m. or later and he would see the patients until late in the evening.

404. S.K.'s patient examinations, when he conducted examinations at all, were perfunctory and standardized and not necessarily relevant to the patients' complaints. Diagnostic tests, even if ordered, rarely resulted in any change in treatment or pain management. Instead, S.K. prescribed opioids, typically in a set monthly dosage of 120 pills, at the first visit and every subsequent visit, without accounting for differences in patient history, without exploring alternative treatment options, without conducting legitimate urine drug screenings, without conducting random pill counts, and all the while ignoring warning signs of addiction and abuse in favor of continuing opioid prescribing.

405. S.K. ran a cash-based clinic and generally charged a flat rate of $200 cash per patient visit. Nearly 40 percent of S.K.'s controlled-substance prescriptions filled at Walmart pharmacies were paid for in cash, another red flag of abuse. Even patients who carried insurance paid for their prescriptions in cash. S.K.'s business grew by word of mouth within the pill-seeking community around New Bern, North Carolina.

406. Walmart pharmacists recognized many of the warning signs and red flags that indicated that S.K. was operating a pill mill.

407. As early as March 2013, Walmart pharmacists emailed the compliance team to report that S.K.'s prescribing patterns were alarming. A Walmart pharmacist at Store 1300 in New Bern, North Carolina, spoke to and then emailed a Market Health and Wellness Director, seeking guidance because "SOP [standard operating procedure] is not enough-they assure patient relationship and provide diagnosis codes, but there is no way that many 25 year olds need 120 to 240 oxycodone per month." The pharmacist reported that four competitor pharmacies in the area were no longer accepting S.K.'s prescriptions because they questioned whether there was a

"legitimate medical need." The email was sent to T.K., a senior director on the compliance team, and then to B.N., who wrote back with the boilerplate POM 1311 response.

408. S.K. began sending patients to more distant pharmacies when local pharmacies started rejecting his prescriptions. Walmart's compliance team learned about this troubling practice in refusal-to-fill forms submitted by Walmart pharmacists between August 2013 and October 2013. In August 2013, a pharmacist at Store 3864 in Jacksonville, North Carolina, about 35 miles from New Bern, reported that a customer said S.K. had "told him to come to our particular store." The next month, a pharmacist at Store 1236 in Goldsboro, North Carolina, more than 50 miles from New Bern, reported that the patient had "let it slip that [another national retail pharmacy] refused to fill the rx" before the patient presented it to Walmart. And in October 2013, a patient admitted to a Walmart pharmacist in Havelock, North Carolina, about 20 miles from New Bern, that "other pharmacies will not fill for this doc[t]or either."

409. In another clear sign that S.K. was not operating a legitimate medical office, a Walmart pharmacist at Store 3825 in Havelock, North Carolina, reported in an October 29, 2013, refusal-to-fill form that S.K. was "known to give large quantities of C2 [Schedule II] prescriptions and no other rx's," and that S.K.'s office was not open during the day for pharmacists to call for verification. S.K. was, however, available late at night and answered his own phone to validate prescriptions.

410. A Walmart pharmacist at Store 3864 in Jacksonville, North Carolina, recognized that S.K.'s attempts to validate his prescriptions were insufficient because S.K.'s prescribing practices showed unresolved red flags. In a refusal-to-fill form submitted by that pharmacist in August 2013, the pharmacist reported that S.K. "is always in the office after hours up to 9 PM to answer the phone himself to say prescriptions are valid." In addition, the patient had driven a

long way to the pharmacy and had been to four different pharmacies in the preceding five months.

411. Between July 2013 and July 2015, multiple Walmart pharmacists submitted to the Walmart compliance team more than 70 refusal-to-fill forms for S.K., listing a catalogue of unresolved red flags, including that S.K. prescribed large quantities of opioids, lacked valid relationships with his patients, and kept odd hours. Other red flags included that some of S.K.'s patients traveled long distances to fill their prescriptions at Walmart; paid in cash; were hostile, including one customer who "demand[ed] narcotics," requiring that security be called; were very irritable or became upset; and were pharmacy shoppers.

412. In July 2014, Walmart's compliance team was again alerted that S.K. was telling his patients that other area pharmacies had stopped filling his prescriptions. Specifically, a pharmacist at Store 3864 reported learning that S.K. "tells his patients that only Wal-Mart will fill his prescriptions" and "all other pharmacies in the area refuse to fill for this prescriber."

413. Indeed, around this same time, S.K. gave one of his patients—who was at that time working as a confidential source for law enforcement—a list of pharmacies that he believed would still fill his prescriptions. Walmart was second from the top of that list. Walmart, for years, persisted in filling illegal prescriptions S.K. had written.

414. By October 29, 2013, Walmart's compliance team, including at least B.N., knew that S.K.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from October 29, 2013, through June 18, 2016, of approximately 775 of S.K.'s invalid controlled-substance prescriptions. The compliance team corporately blocked S.K. on January 19, 2018.

415. S.K. was arrested in June 2016 on federal drug-trafficking charges arising from his opioid prescriptions. He was convicted of numerous federal felony charges, including unlawfully prescribing oxycodone outside the scope of professional practice and without a legitimate medical purpose and, in September 2020, was sentenced to 20 years of imprisonment.

V.S.: A "shady doctor" who "writes only controlled medications for every patient"

416. V.S. practiced in Bradenton, Florida, as a gynecologist. Upon retiring from his gynecology practice, he worked part-time at a pain clinic. The pain clinic actively advertised to cash patients, highlighted quick service, and called over-the-counter aspirin "useless and awful for your body." It also publicly solicited names of pharmacists and pharmacies in Bradenton and Sarasota that refused to fill V.S.'s prescriptions and advised patients to use two specific mail-in pharmacies to fill Schedule II pain medications.

417. As early as December 2013, a Walmart pharmacist at Store 528 in Bradenton, Florida, filled out a refusal-to-fill form alerting Walmart's compliance team to V.S.'s high-risk prescribing practices and declining to fill prescriptions for oxycodone and methadone because the patient, E.T., was also on Xanax, which in combination with oxycodone and methadone created a "high risk of respiratory depression."

418. In 2014, several Walmart pharmacists alerted the compliance team to concerns about V.S.'s prescribing practices. On a refusal-to-fill form submitted in February 2014, a Walmart pharmacist at Store 1171 in Sarasota, Florida, flagged that V.S. was acting out of his previous scope of practice. Two months later, in April 2014, another Walmart pharmacist at Store 1171 in Sarasota, Florida, flagged V.S.'s background, noting the unusual fact that V.S. was a gynecologist working at a pain clinic. In May 2014, the same pharmacist submitted a refusal-to-fill form reporting that V.S.'s therapies did not appear to be individualized and that V.S.

"writes only for c-2's," that is, only for Schedule II controlled substances. Similarly, in June 2014, another pharmacist reported that V.S. "writes only controlled medications for every patient seen." On September 27, 2014, a third pharmacist submitted a refusal-to-fill form describing V.S. as a "[s]hady doctor."

419. Walmart pharmacists further reported that some of V.S.'s patients appeared to them to be drug-seekers rather than legitimate pain patients. For example, a Walmart pharmacist at Store 3474 in Bradenton reported on January 6, 2014, that two customers, who were "slurring their words and showed signs of drug seeking behavior/narcotic abuse," arrived together, one with a prescription from V.S. for oxycodone, methadone, Soma, and Valium, a "cocktail of abuse," according to the pharmacist, and the other saying that he also had his medications filled at that pharmacy. Despite observing these "signs of drug seeking behavior," the pharmacist at Store 3474 filled C.C.'s prescriptions for Soma and Valium. And to complete the "cocktail of abuse," C.C. went to Walmart Store 1171 in Sarasota, Florida, where she filled her prescription for oxycodone 30mg (90 tablets).

420. Between January and July 2014, Walmart pharmacists from two different Florida pharmacies reported in refusal-to-fill forms that V.S.'s patients appeared "impaired," "glassy eyed," "possibly intoxicated," or "possibly inebriated," or that they slurred their speech.

421. While certain Walmart pharmacists refused to fill V.S.'s prescriptions and raised their concerns with Walmart's compliance team, Walmart continued to fill thousands of V.S.'s controlled-substance prescriptions, even for customers whose prescriptions had previously been refused.

422. The filling history of Walmart customer E.T.'s prescriptions written by V.S. illustrates how pharmacy shopping took place among Walmart pharmacies.

Date	Store Number	Store Location	Prescription	Filled /Refused	Reason for Refusal
12/14/2013	528	Bradenton, FL	methadone 10mg, oxycodone 20mg	refused	"inappropriate therapy per eforcse patient is taking methadone oxycodone and xanax patient fills these at several different pharmacies per pain management guidelines methadone should not be taken with other opioids and benzodiazepines dt high risk of respiratory depression"
12/16/2013	1004	Bradenton, FL	methadone 10mg	Filled	
12/26/2013	5727	Bradenton, FL	Oxycontin 20mg	refused	"other than legitimate patient presented a very dirty prescription thru the drivethru patient has never had anything filled here before i am not familiar with this doctor or this patient"
1/11/2014	1171	Sarasota, FL	oxycodone 30mg	Filled	
1/17/2014	1004	Bradenton, FL	methadone 10mg	Filled	
2/5/2014	528	Braden River, FL	alprazolam 1mg	Filled	
2/18/2014	1171	Sarasota, FL	oxycodone 30mg	refused	"Doctor prescription outside of previous scope of practice"
4/3/2014	1004	Bradenton, FL	alprazolam 1mg	Filled	
4/4/2014	1004	Bradenton, FL	methadone 10mg	filled	
4/12/2014	1171	Sarasota, FL	Oxycontin	refused	"doctor gynecologist working at pain clinic"
4/18/2014	1171	Sarasota, FL	methadone 10mg	refused	"early refill; early refill via e forsce"
4/30/2014	1004	Bradenton, FL	alprazolam 1mg	Filled	
5/5/2014	1171	Sarasota, FL	oxycodone 30mg	refused	"Refill too soon"

Date	Store Number	Store Location	Prescription	Filled /Refused	Reason for Refusal
5/9/2014	1004	Bradenton, FL	methadone 10mg	Filled	
5/23/2014	1171	Sarasota, FL	oxycodone 30mg	refused	"large quantity; this doctor writes only controlled medications for every patient seen"
5/28/2014	1004	Bradenton, FL	alprazolam 1mg	filled	
6/6/2014	1004	Bradenton, FL	methadone 10mg	Filled	
6/23/2014	1004	Bradenton, FL	methadone 10mg, Percocet (oxycodone-acetaminophen) 10/325mg	refused	"too soon according to eforce; patient cannot wait until get prescription verify and fill"
6/26/2014	1004	Bradenton, FL	oxycodone-acetaminophen 10/325mg; alprazolam 1mg	Filled	
7/4/2014	1004	Bradenton, FL	methadone 10mg	Filled	
7/21/2014	1004	Bradenton, FL	alprazolam 1mg	Filled	
7/28/2014	528	Bradenton, FL	oxycodone-acetaminophen 10/325mg	refused	"Too soon"
8/1/2014	1004	Bradenton, FL	methadone 10mg	Filled	
8/26/2014	1004	Bradenton, FL	alprazolam 1mg, oxycodone-acetaminophen 10/325mg	Filled	
8/29/2014	1004	Bradenton, FL	methadone 10mg	Filled	
9/24/2014	1004	Bradenton, FL	alprazolam 1mg	Filled	
9/26/2014	1004	Bradenton, FL	methadone 10mg	Filled	
9/27/2014	1171	Sarasota, FL	oxycodone 15mg	refused	"shady pt; shady doctor"

423. Then, from January 2015 until December 2016, Walmart Store 1004 continued filling controlled-substance prescriptions for E.T., including 10 prescriptions for methadone 10mg (90 or 120 tablets each) and eight prescriptions for oxycodone 15mg (120 tablets each).

424. By September 27, 2014, Walmart's compliance team, including at least B.N., knew that V.S.'s prescriptions were issued outside the usual course of professional practice and

were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling, from September 27, 2014, through January 22, 2018, of approximately 2,232 of V.S.'s invalid controlled-substance prescriptions.

425. V.S. let his Florida medical license expire in January 2018. In May 2018, a Walmart employee in the compliance team was notified that V.S. no longer held a state license to practice medicine or an active DEA registration.

W.W.: A "pill mill prescriber" for "drug-seekers"

426. W.W. was a doctor who had been licensed to practice in a number of states, including Florida, Tennessee, Colorado, Washington, and Kentucky. From at least 2013 until 2015, he practiced in Estero and Fort Myers, Florida. Immediately before that, W.W. served as the director of an unlicensed pain clinic in Knoxville, Tennessee. At the clinic, W.W. was supposed to supervise advanced practice nurses, but he gave the nurses "no guidance" whatsoever and did not review patient charts. The clinic engaged in egregious prescribing habits, including continuing to prescribe a patient opiates and benzodiazepines after a positive urine drug screen for cocaine. In 2013, W.W. also prescribed controlled substances from a clinic in Pikeville, Kentucky.

427. Beginning in 2013, pharmacists at multiple Walmart stores reported egregious and obvious signs that W.W. was operating a pill mill. In May 2013, a pharmacist at Store 3417 in Naples, Florida, reported, in a refusal-to-fill form, "History with patients from this office – we get frequent calls seeking this medication [oxycodone 30mg], daily nagging, patients arriving in car loads, hysteria at drop off, patients sitting in parking lot waiting for FedEx to come; will not fill from this office anymore …." Later in 2013, pharmacists at Store 3417 repeatedly reported, in refusal-to-fill forms, the store's problems with drug-seekers who would come from W.W.'s office in groups.

428. On July 31, 2013, a pharmacist from another Walmart pharmacy, Store 5321 in Fort Myers, Florida, reported that W.W. was "practicing outside of scope" and that he was "well reputed for over prescribing C-2 [Schedule II] narcotics." About a month later, on September 3, 2013, another pharmacist at Store 5321 stated, in a refusal-to-fill form, that W.W. was "known for patterned high dose narcotics in the community." Over a year later, W.W.'s prescriptions were still being presented at Store 5321, and, in January 2015, a pharmacist at Store 5321 again reported that W.W. practiced outside his scope and was "known as a pill mill doctor."

429. In December 2013, yet another Walmart pharmacy, Store 5391 in Naples, Florida, reported that W.W. was a "know[n] pill mill prescriber in the [F]ort [M]yers area." A pharmacist working at Store 5391 had submitted a refusal-to-fill form earlier that year, in June 2013, reporting the details showing that W.W. was running a pill mill: W.W. accepted only cash; he engaged in pattern prescribing for large quantities of oxycodone until he switched to hydromorphone; and he deployed a "newer technique" of splitting prescriptions in half to "give the appearan[]ce of smaller quantities being dispensed."

430. Pharmacists from Stores 3417 and 623 reported in at least four refusal-to-fill forms in 2013 that W.W. "continually prescribes narcotics [and] not much else" and that his patients were doctor and pharmacy shoppers, some of whom appeared "sever[e]ly impaired and high."

431. By March 2014, a pharmacist from yet another Walmart pharmacy, located in Store 987 in Fort Myers, Florida, had concluded that W.W. "does not prescribe for purposes that I feel are legit[i]mate."

432. The Tennessee Board of Medical Examiners revoked W.W.'s medical license in January 2014 as a result of his failure to supervise nursing staff in what the board described as

"egregious prescribing habits" related to controlled substances. W.W.'s licenses to practice medicine in Colorado, Kentucky, Washington, and Florida were later suspended or revoked.

433. By December 2014, Walmart's compliance team knew, from a refusal-to-fill form submitted by Store 3417 in Naples, Florida, that W.W.'s license had been suspended by two states "due to mishandling of controlled substances." The same pharmacy reported similar red-flag information in January 2015.

434. By September 3, 2013, Walmart's compliance team, including at least B.N., knew that W.W.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. They chose to act and not act in ways that led to the filling of approximately 561 of W.W.'s invalid controlled-substance prescriptions from September 3, 2013, through June 4, 2015. Approximately 108 of those prescriptions were filled from January 1, 2015, through June 3, 2015, after Walmart's compliance team had been informed in December 2014 of the suspension of W.W.'s medical license in two states.

435. On June 15, 2015, the Florida Board of Medicine suspended his license, and DEA thereafter revoked his registration.

Z.B.: A "questionable" prescriber sending patients to fill at Walmart

436. Z.B. was an anesthesiologist who operated a pain management clinic in Tampa, Florida. His cluttered, disheveled office had all the outward features of a stereotypical "pill mill" clinic, with large numbers of patients who drove in groups for long distances to appointments. The great majority of Z.B.'s patients had criminal histories, and approximately half of his patient population had criminal drug histories. Patients in the crowded waiting area could be seen sleeping, losing consciousness, and falling out of their chairs, and they could be overheard openly discussing illegal narcotics. Patients paid cash for excessively high dosages of opioids that were prescribed after little to no clinical evaluation. Z.B. kept a pet Cockatoo named

"Cyrus" in his exam room and often spent more time talking to his bird than to patients.

437. Walmart pharmacists repeatedly informed Walmart's compliance team, through refusal-to-fill forms, of unresolved red flags indicating that Z.B.'s patients were not legitimate pain patients. As early as December 3, 2013, a Walmart pharmacist at Store 959 in Bushnell, Florida, reported in a refusal-to-fill form Z.B. as a "questionable" prescriber after rejecting a prescription written by Z.B. for oxycodone and morphine sulfate.

438. In particular, Walmart pharmacists reported to Walmart's compliance team that Z.B.'s patients appeared to be pharmacy shoppers who brought prescriptions to Walmart because other pharmacies would not fill their prescriptions. For example, a pharmacist from Store 959 reported on two refusal-to-fill forms that the individual was "travelling long distance to get rx filled" and "says local pharmacies doesn[']t want to fill his rx." On December 28, 2013, a pharmacist at Store 960 in Dunnellon, Florida, refused to fill a Dilaudid prescription issued by Z.B. due to "multiple pharmacies and n[a]rcotics" involved.

439. Walmart pharmacists reported to the compliance team, in at least four additional refusal-to-fill forms submitted in 2014 and 2015 from Store 959, that multiple individuals for whom Z.B. had written prescriptions traveled long distances to the Bushnell pharmacy to get their prescriptions filled.

440. Refusal-to-fill forms submitted from other Walmart pharmacies in 2013 and 2014 similarly alerted Walmart's compliance team that individuals whose controlled-substance prescriptions were issued by Z.B. were seeking out Walmart pharmacies to fill those prescriptions. For example, a Walmart pharmacist at Store 1245 in Lakeland, Florida, reported that a Z.B. patient had said to the pharmacist that his friend told him to go to that Walmart pharmacy. The pharmacist noted that the patient had been using other pharmacies in Tampa, and

the pharmacist refused to fill the prescription because the patient "lives in Ocala, went to a doctor in Tampa and came here to get his prescription." Pharmacists in Orlando and Ocala also encountered Z.B. patients who had "passed many pharmacies" on the way to fill their prescriptions at Walmart. A pharmacist in Bushnell, Florida, refused to fill a prescription issued by Z.B. because the patient and doctor both were from out of the area "> 25 miles." A Walmart pharmacist in Findlay, Ohio, refused to fill a Z.B. prescription for oxycodone 30mg that had been written in Tampa, Florida, two days before it was presented, taking pains to note the following: "asked why patient was filling out of town, story was very fishy" and "red flag to begin with oxy 30[mg] from florida."

441. When some Walmart pharmacists refused to fill Z.B.'s prescriptions, some customers simply took Z.B.'s prescriptions to other Walmart pharmacies, which then filled the prescriptions. For example, on July 28, 2013, Store 1085 in Port Richey, Florida, refused to fill an oxycodone 15mg prescription for customer E.S. Three days later, Walmart Store 2081 in Clearwater, Florida, filled that prescription. Walmart pharmacies continued filling E.S.'s oxycodone 15mg prescriptions until February 14, 2014, when a Walmart pharmacist at Store 1084 in Orlando, Florida, refused to fill the prescription. Four days later, the same Walmart pharmacy filled E.S.'s oxycodone 15mg prescription. From September 2013 until April 2016, three different Walmart pharmacies filled E.S.'s oxycodone 15mg prescriptions.

442. As another example, on October 23, 2014, Walmart Store 959 in Bushnell, Florida, filled customer T.H.'s prescriptions written by Z.B. for hydromorphone 8mg and methadone 10mg. Then, the following month, on November 19, 2014, and again on November 21, 2014, Store 959 refused to fill these two prescriptions for T.H. From March to May 2015, Store 697 in Ocala, Florida, dispensed these two drugs to T.H. on three occasions. In late 2015,

T.H. returned to Store 959, where the pharmacists resumed filling her hydromorphone 8mg and methadone 10mg prescriptions written by Z.B.

443. In June 2016, the Walmart compliance team analyzed the controlled-substances prescriptions, and in particular oxycodone 30mg, dispensed at Store 5654 in Tampa, Florida. The analysis determined a need for a remediation plan, including in-store training. The compliance team's analysis revealed that, during a six-month period, the store's dispensing of oxycodone 30mg increased by 143 percent and Z.B. tied with another prescriber for second-highest prescriber of the medication at that location. Seventy-five percent of Z.B.'s oxycodone 30mg prescriptions were for 120 tablets or more.

444. In August 2016, the Walmart compliance team analyzed the controlled-substance prescriptions dispensed at Store 5694, also in Tampa, Florida, and in particular the extremely high volume of oxycodone 30mg tablets that had been filled at that location. The store's pharmacy manager reported that patients asked for a specific pharmacist, D.D., by name and waited for her to fill their prescriptions. During this analysis, Walmart compliance determined that Z.B. was the top prescriber of oxycodone 30mg at Store 5694. Z.B. prescribed 14 percent of the prescriptions for oxycodone 30mg filled there. Walmart further determined that 70 percent of his oxycodone 30mg prescriptions were for 120 tablets or more. Forty-three percent of Z.B.'s prescriptions were for Schedule II controlled substances and the top drugs he prescribed were all high-dose opioids (oxycodone 30mg, hydromorphone 8mg, and methadone 10mg).

445. By December 3, 2013, Walmart's compliance team, including at least B.N., knew that Z.B.'s prescriptions were issued outside the usual course of professional practice and were being presented to Walmart pharmacies. For years, until the team corporately blocked Z.B. on May 1, 2017, they chose to act and not act in ways that led to the filling, from December 3, 2013,

through April 29, 2017, of approximately 2,627 of Z.B.'s invalid controlled-substance prescriptions. Approximately 468 of those prescriptions were paid for in cash, and approximately 136 were dispensed to patients from states other than that of Z.B. and/or the pharmacy.

2. Walmart pharmacists unlawfully filled thousands of prescriptions that they knew were invalid.

446. During the Dispensing Violations Period, certain Walmart pharmacists filled controlled-substance prescriptions that they knew, at a minimum through their willful blindness, were invalid.

a. Walmart pharmacists were trained and instructed to identify red flags.

447. Walmart pharmacists filled numerous prescriptions with obvious combinations of red flags showing that the prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. These red flags related to the prescription itself, the prescriber, or the patient.

448. Walmart pharmacists knew that they were required to assess these prescriptions, recognize the red flags, and attempt to resolve the red flags in determining whether the prescriptions were valid.

449. First, pharmacists were professionally trained to recognize and assess red flags and to determine whether a prescription was valid. For example, schools of pharmacy generally included, in their standard curricula, courses covering red flags. Pharmacists were trained that they could conclude that a prescription was invalid even if it had been signed by a prescriber.

450. Second, it was recognized in the pharmacy profession that pharmacists had an obligation to assess red flags and to determine whether a prescription was valid. This professional obligation was consistent with pharmacists' corresponding responsibility, long

imposed by federal law in 21 C.F.R. § 1306.04(a), to determine whether a prescription was issued for a legitimate medical purpose and in the usual course of professional practice.

451. Third, pharmacists generally had professional experience in assessing whether red flags showed that a prescription was invalid.

452. Fourth, Walmart's training and written policies directed pharmacists to examine whether controlled-substance prescriptions showed red flags and then to determine whether the prescriptions were valid. The August 2013 "red flags document," *see supra* ¶¶ 111-116, listed multiple warning signs related to the prescriber, prescription, and patient. The training instructed pharmacists to "consider each of these characteristics for every controlled substance that is brought to your pharmacy." Additionally, POM 1311 (2015) directed pharmacists to "review each prescription to determine if it was written for a legitimate medical purpose." Like the earlier training, POM 1311 (2015) identified a list of red flags about prescribers, patients, and the prescription.

b. Walmart pharmacists knew that certain prescriptions were invalid because of the prescriber or other red flags.

453. As set forth below, certain Walmart pharmacists filled prescriptions that they knew were invalid. Some knew that the prescriptions had been issued by pill-mill prescribers based on red flags indicating that the prescriber was operating outside the usual course of professional practice. Some filled prescriptions that were clearly invalid based on a combination of obvious red flags.

i. Walmart pharmacists knew certain prescriptions were issued by pill-mill prescribers who practiced outside the usual course of professional practice.

454. Walmart pharmacists filled certain prescriptions they knew were invalid based on their knowledge of red flags revealing that the prescriber was acting outside the usual course of

professional practice, as illustrated by the examples below.

Fills despite knowledge about G.H. and R.M.

455. Walmart pharmacists at certain stores knew about the pill-mill practices of G.H. and R.M., based in Roland, Oklahoma. *See supra* ¶¶ 276-286.

456. For example, on September 25, 2013, the pharmacy manager for Store 8134 in Fort Smith, Arkansas, was sufficiently concerned about the prescribing practices of the doctors at R.M.'s clinic that he reached out to a Walmart market manager in the Health and Wellness Division. The pharmacy manager identified both G.H. and R.M. as the doctors responsible for the clinic's improper prescribing. He explained that "the problem" with R.M.'s clinic had "grown over the last 2 years," and that he was "feeling more uncomfortable about all scripts that come from" the clinic.

457. The pharmacy manager admitted, however, that even though the pharmacy was armed with this knowledge, the pharmacists continued to fill prescriptions issued by G.H. and R.M. The pharmacy manager explained that "depending on how long it might take co[r]porate to decide on what to do, we might start to refuse to fill prescriptions for some patients." After September 25, 2013, despite the pharmacy manager's acknowledgement that he was "uncomfortable about all scripts" issued by G.H. and R.M., his pharmacy filled approximately 722 controlled-substance prescriptions written by those prescribers.

Fills despite knowledge about H.D.

458. Walmart pharmacists at certain stores knew about the pill-mill practices of H.D., based in Sherman, Paris, and Sulphur Springs, Texas. *See supra* ¶¶ 290-299.

459. Certain Walmart pharmacists in Texas repeatedly notified Walmart's compliance team about H.D.'s pill-mill practices. In those communications, the pharmacists made clear that they were still filling prescriptions issued by H.D. For example, on February 6, 2015, a

pharmacy manager from Store 147 in Denison, Texas, sent an email to Walmart's compliance team about H.D.—on behalf of her own pharmacy as well as two others in the areas—explaining that she and other pharmacists "are all concerned about our jobs and about filling for a pill mill doctor," that her understanding was that other chain pharmacies were refusing to fill prescriptions issued by H.D., and that "I am in my 29th year with [W]almart and have never had a situation this bad with a doctor." Another pharmacist at Store 147 sent an email the same day commenting that "[f]illing for [H.D.] is a risk that keeps me up at night."

460. After the pharmacy manager at Store 147 described H.D. as a "pill mill doctor" and sought guidance on behalf of three pharmacies, pharmacists at those three pharmacies filled over 4,000 controlled-substance prescriptions written by H.D.

Fills despite knowledge about P.T.

461. Walmart pharmacists at certain stores knew about the pill-mill practices of P.T., based in Milford, Delaware. *See supra* ¶¶ 355-363.

462. Staff at a Walmart pharmacy in Milford knew that P.T. was routinely issuing identical controlled-substance prescriptions even though he was not a pain management specialist. On January 10, 2014, the pharmacy manager from Store 1741 in Milford, Delaware, informed a regional supervisor in an email that she had spoken with the manager of Delaware's prescription monitoring program and learned "interesting information" about P.T. that "needs to be forward [sic] to all pharmacist[s] and our compliance and ethical Department." The manager told the field supervisor that two national retail pharmacies and a local pharmacy were no longer filling P.T.'s prescriptions. Additionally, although P.T. claimed to be a pain management doctor, "according to the board of pharmacy he is not." By January 2014, Walmart pharmacists in Delaware had submitted at least 25 refusal-to-fill forms for P.T.'s prescriptions, and 10 of those refusal-to-fill forms were submitted by the pharmacy manager.

463. The pharmacy manager reported P.T.'s unprofessional practices to others. Later in January 2014, DEA diversion investigators surveyed pharmacists in the Milford area and spoke with the manager and another pharmacist at Store 1741. The manager explained that she knew that P.T. did not have credentials to practice as a pain management physician.

464. The pharmacy manager's comments indicated that the pharmacy was still filling prescriptions issued by P.T. She reported that there was an influx of P.T. patients on Thursdays, probably because P.T.'s office was closed on Fridays. She observed that his patients arrived within three minutes of one another and "if the pharmacy does not have the medication . . . the word spreads in the parking lot and patients attempt to go to other pharmacies to get their prescriptions filled." She told the investigators that most patients paid cash for their prescriptions even though they had Medicaid. She and the other pharmacist explained that many individuals from the same family received the same medication in the same quantity from P.T., and that multiple people from the same address received the same medications.

465. After January 15, 2014, despite this knowledge of P.T.'s pill-mill practices, Walmart pharmacists at Store 1741 filled more than 160 controlled-substance prescriptions issued by P.T.

Fills despite knowledge about R.K.

466. Walmart pharmacists at certain stores knew about the pill-mill practices of R.K., based in Mt. Carmel and Shamokin, Pennsylvania. *See supra* ¶¶ 367-379. R.K.'s prescribing practices were common knowledge in Mt. Carmel and Shamokin. As one former patient explained, R.K. was the "go to" for pain pills.

467. The pharmacists at Store 2481 in Coal Township, Pennsylvania, knew about R.K.'s improper prescribing practices, but continued to fill his prescriptions. Store 2481's pharmacy manager was interviewed by DEA on August 25, 2015, after the store filled a

prescription by R.K. for a customer eight days after the customer had died. The pharmacy manager explained that most of the prescriptions that were refused at Store 2481 were issued by R.K. He also said that many patients attempted to refill narcotic prescriptions early and that R.K. wrote many narcotic prescriptions for the same patient just days apart. The pharmacy manager later stated that the four pharmacists who worked at the store consulted with each other. On August 28, 2015, one of the other pharmacists from Store 2481 reported to DEA that it was not uncommon for the pharmacy to sell out of narcotics on the weekends because of the high volume of narcotics that R.K.'s patients were attempting to fill. On Saturday mornings, R.K.'s patients would line up outside the pharmacy before it opened. After August 28, 2015, despite their knowledge of R.K.'s pill-mill practices, the pharmacists at Store 2481 filled 2,861 controlled-substance prescriptions written by R.K.

468. Pharmacists at another Walmart pharmacy also filled R.K.'s prescriptions despite knowing about his pill-mill practices. In September 2016, the Walmart pharmacy manager for Store 2535 in Saint Clair, Pennsylvania, emailed a field supervisor to inform her that R.K. "is currently under investigation by the DEA for what we believe is a pill mill operation." The pharmacy manager wrote that "[another pharmacy chain] has sent him a blanket denial letter." The pharmacy manager stated that "if we continue to accept [R.K.'s] prescriptions we are putting pharmacists and Walmart in a bad situation legally as the levels are beyond normal usage."

469. After the date that Store 2535's pharmacy manager reported that the pharmacists believed R.K. was running a "pill mill operation," Walmart pharmacists at the store filled approximately 139 Schedule II controlled-substance prescriptions written by R.K.

Fills despite knowledge about R.W.

470. Walmart pharmacists at certain stores knew about the pill-mill practices of R.W. *See supra* ¶¶ 395-400.

471. By 2014, Walmart pharmacy managers in Texas were aware of R.W.'s pill-mill prescribing practices. For example, in February 2014, the pharmacy manager for Sam's Club Store 4906 in McKinney, Texas, suggested that Walmart stop filling any prescriptions from R.W. "so we are not put in any crazy situation." Walmart pharmacy employees in the area sent emails to Walmart managers regarding red flags about R.W.'s prescribing habits through at least July 2016.

472. Notwithstanding this common knowledge at Walmart pharmacies in R.W.'s area, the pharmacies continued to fill his prescriptions. After the date that the pharmacy manager at Store 4906 stated that filling R.W.'s prescriptions could put the pharmacy in a "crazy situation," that pharmacy filled approximately 899 controlled-substance prescriptions written by R.W.

473. As another example, at Store 206 in McKinney, Texas, a pharmacist explained that the pharmacy had identified multiple red flags revealing that R.W. was not acting in the usual course of professional practice. The pharmacist observed that R.W. routinely issued large hydrocodone prescriptions for individuals who traveled long distances and that other pharmacies had stopped filling R.W.'s prescriptions. The pharmacist explained that the pharmacists at Store 206 had questioned R.W.'s prescriptions as early as approximately December 2015, but "we fill his prescriptions a lot." She explained that she had been told that the pharmacy could not make a blanket decision to refuse to fill his prescriptions; as a result, she continued to fill R.W.'s prescriptions, despite her knowledge of his pill-mill practices.

Fills despite knowledge of J.U.

474. In November 2015, a Walmart pharmacy manager in Missouri reported that a doctor, J.U., was prescribing numerous Schedule II controlled-substance prescriptions for individuals who "we do not believe have a medical need for them." The pharmacy manager observed that "red flags are everywhere." For example, the manager noted that J.U. frequently

called ahead and "always late in the evening" to see what Schedule II drugs were in stock, and the calls usually related to patients who themselves raised red flags, such as individuals "we know have been fired from other doctors or have a history of abuse," or to replace "stolen" prescriptions for patients the pharmacy had never seen. The Missouri State Board of Registration for the Healing Arts later revoked the doctor's medical license, finding, among other things, that the physician had issued patients "excessive controlled substances without conducting sufficient physical examination or maintaining adequate records."

475. The pharmacy manager admitted that, notwithstanding the knowledge that the prescriber was not adhering to the usual course of professional practice, the pharmacy filled seven Schedule II controlled-substance prescriptions by the prescriber between September 2015 and November 2015. Moreover, while the pharmacy manager stated in unequivocal terms that "[n]o prescriptions are to be filled from [J.U.] going forward," Walmart pharmacists at the same store continued to fill Schedule II controlled-substance prescriptions for this doctor through January 2017.

ii. Walmart pharmacists knew certain prescriptions were invalid based on combinations of obvious red flags.

476. Walmart pharmacists also filled invalid prescriptions calling for such dangerous combinations of controlled substances, often in combination with other red flags, that the pharmacists filling such prescriptions did so knowing that the prescriptions were invalid. Some of those pharmacists were willfully blind to the prescriptions' invalidity: they chose not to resolve the obvious red flags before filling the prescriptions, despite their subjective awareness of the high probability that the prescriptions were invalid.

477. Set forth below are examples of such combinations of controlled substances.

(a) Red Flag Combination No. 1: Dangerous combinations of opioids

478. As trained pharmacists were aware, and as Walmart itself recognized in POM 1311 (2015), prescriptions could show obvious red flags on their face when they were "presented in a combination that can cause medical complications" or were "for an unusually large quantity or high starting dose."

479. One combination that presented obvious red flags, but that Walmart pharmacists repeatedly filled, was multiple immediate-release opioids prescribed together or close in time. Immediate-release opioids (in contrast to extended-release or long-acting opioids) release the drugs more quickly into the bloodstream and generally have a shorter analgesic effect than extended-release drugs. POM 1311 (2017) identified prescriptions for drugs with "similar effects (e.g. multiple long acting or multiple short acting opioids)" as a red flag.

480. Some Walmart pharmacists recognized these duplicative prescriptions for multiple immediate-release opioids as dangerous and refused to fill them.

481. For example, in December 2012, an Orlando-area pharmacist refused to fill a prescription for oxycodone 30mg and oxymorphone-IR 10mg because "similar SA [short-acting] narcotic filled within 11 days prior to this Rx." For the same reason, a pharmacist in Oklahoma refused to fill a prescription in April 2015 for oxycodone 15mg because the individual had received the same short-acting opioid in a 30mg strength from another pharmacy, explaining, "I don't know a reason to be on both."

482. Between June 2013 and June 2018, Walmart pharmacists filled thousands of prescriptions for multiple immediate-release opioids on the same day or close in time, in some cases for not only two but three or more immediate-release drugs, often in combination with other red flags.

483. As an example, for customer D.W., a Walmart pharmacy in Arkansas dispensed

oxycodone 30mg (126 to 222 tablets) and oxycodone 15mg (84 to 148 tablets) nearly every month from January 1, 2015, through August 31, 2015. D.W.'s prescriptions were written by an Oklahoma prescriber, J.R. For at least five other individuals for at least three months in a row, Walmart filled prescriptions issued by J.R. for the same duplicative opioids (oxycodone 15mg and 30mg). J.R. voluntarily surrendered her Oklahoma medical license in July 2017 rather than contesting allegations that, among other things, she routinely issued prescriptions for Schedule II controlled substances without examining the patients.

484. Another dangerous combination that Walmart pharmacists dispensed was an immediate-release opioid and methadone, another powerful opioid.

485. Compared to an immediate-release opioid, methadone generally takes longer for a user to feel its effects, but those effects may last longer. For this reason, when taken in combination with an immediate-release opioid, methadone can be particularly dangerous; its long-acting properties may lead the user to take higher amounts of immediate-release opioids to achieve the desired euphoria or painkilling effects in the short term, but the long-term depressive effects of methadone can lead to excessive respiratory depression and death when combined with the effects of another opioid.

486. A Walmart pharmacist recognized the dangers of this combination and therefore, in January and again in March 2014, refused prescriptions for methadone and oxycodone and for methadone and hydromorphone, noting each time that "[m]ethadone should not be taken with other opioids or with benzodiazepines per pain management guidelines and per gold standard [due to] high risk of respiratory depression."

487. Other Walmart pharmacists, however, filled prescriptions for both an immediate-release opioid and methadone at the same time or close in time despite the obvious dangers of

the combination, often in combination with other red flags.

488. By way of example, for customer C.B., Walmart dispensed at least 240 methadone 10mg tablets plus at least 108 oxycodone 30mg tablets every month from June 2017 through July 2018. The same Walmart pharmacy dispensed all of those drugs to C.B. and always dispensed the methadone and oxycodone together. On the same day that Walmart dispensed those dangerous combinations to C.B., the same Walmart pharmacy dispensed the same dangerous combinations—in the same quantity and days' supply and based on prescriptions written by the same prescriber—to M.B., who shared the same last name as C.B. and, according to Walmart's own data, lived at the same address.

489. All told, from June 2013 forward, Walmart pharmacists filled thousands of prescriptions comprising the multiple-immediate-release opioids and opioid-methadone combination. The pharmacists filling prescriptions for these dangerous combinations, often revealing other red flags, did so knowing, at a minimum through willful blindness, that the prescriptions were invalid.

(b) Red Flag Combination No. 2: Dangerous "cocktails" of opioids and non-opioids

490. As trained pharmacists were aware, and as Walmart itself recognized in POM 1311 (2015), prescriptions "that represent a 'cocktail' of commonly abused drugs" presented an obvious red flag. A compliance team director explained in an internal email in February 2016 that "[a] cocktail is a red flag that should alert the [pharmacist] to use their professional judgment to refuse to fill the [prescription]."

491. These cocktails included combinations of an opioid and a non-opioid "potentiator" drug—that is, a drug that increased the euphoric effect brought on by opioids, but that also increased the risk of abuse and overdose.

492. Walmart pharmacists filled thousands of prescriptions that fall into four distinct "trinity" categories of combinations of opioid-with-non-opioid prescriptions that on their face presented an obvious red flag. Each category was known to be popular among individuals who were abusing or misusing prescription drugs.

493. Walmart pharmacists filled many of these trinity drug cocktails where additional red flags were present, including, among other things, (i) where a significant supply was prescribed for each drug; (ii) when the filling pattern for the combination continued for multiple months; (iii) when the individual paid in cash; and (iv) when the individual lived in a state different from that of the prescriber or pharmacy. The pharmacists filling prescriptions for these dangerous trinity combinations, often revealing other red flags, did so knowing, at a minimum through willful blindness, that the prescriptions were invalid.

494. **The classic trinity.** First, Walmart pharmacists repeatedly filled prescription drug cocktails consisting of (a) an opioid; (b) a benzodiazepine; and (c) the muscle-relaxer carisoprodol (brand name Soma). This combination, sometimes referred to as the "classic trinity," had been described in DEA administrative decisions as early as 2008. Specifically, the three drugs, taken together, produce enhanced euphoric effects beyond the effect of each individual drug. For similar reasons, however, the classic-trinity combination creates a heightened risk of overdose and death.

495. Some of these classic trinity prescriptions also were written by problem prescribers, such as those described above. By way of example, S.F. was a patient of J.I., whose pill-mill activity is described above. *See supra* ¶¶ 312-320. Pharmacists at Store 1712 in Largo, Florida—the same pharmacy that identified J.I. as a "MILL PILL DR [sic]"—dispensed classic trinity cocktails to S.F. based on prescriptions from J.I. nearly every month for three years

between February 2014 and February 2017. For 25 out of 34 months during this period, Walmart dispensed *both* 120 pills of hydrocodone-acetaminophen 10/325mg (i.e. Vicodin) *and* 60 pills of morphine sulfate extended-release, *in addition* to the potentiating benzodiazepines and muscle relaxers.

496. In another instance, the pharmacy at Store 4341 in Truth or Consequences, New Mexico, dispensed an opioid, a benzodiazepine, and carisoprodol to customer T.A. on the same day or one day apart each month from July through October 2014 and in April and May 2015, based on prescriptions written by J.F., whose pill-mill activity is described above. *See supra* ¶¶ 303-311.

497. **The zolpidem trinity.** Second, Walmart pharmacists repeatedly filled prescriptions for a different but similarly dangerous combination sometimes referred to as the "zolpidem trinity," consisting of (a) an opioid, (b) a benzodiazepine, and (c) the sedative zolpidem (brand name Ambien). The zolpidem trinity is dangerous because the addition of a sedative to two other central-nervous-system depressants may lead to accidental overdose.

498. Some of these zolpidem trinity prescriptions were also issued by problem prescribers, such as those described above. By way of example, from August 2013 through March 2014, Walmart dispensed to customer T.H. zolpidem trinity cocktails every month. Those cocktails—all of which were prescribed by H.D., whose pill-mill activity is described above, *see supra* ¶¶ 290-302—invariably comprised 120 tablets of oxycodone 30mg, the highest strength of immediate-release oxycodone available; 120 tablets of alprazolam 1mg, the second-highest strength of immediate-release alprazolam available; and 30 tablets of 10mg zolpidem, the highest strength of immediate-release zolpidem available. Each month that Walmart dispensed those trinity combinations, the same store also gave T.H. 180 tablets of hydrocodone-

acetaminophen 10/325mg. In five of the eight months, Walmart also dispensed 60 tablets of morphine sulfate extended-release 60mg. In other words, for eight straight months, Walmart gave T.H. 300-360 opioid pills *in addition to* two potentiating drugs that increase the risk of abuse and overdose.

499. Walmart filled its last prescription for T.H. on July 15, 2014, which was for the above quantities and strengths of oxycodone, alprazolam, zolpidem, and morphine sulfate. T.H. died from an overdose on July 25, 2014, nine days later. The cause of death on the toxicology report was listed as probable morphine toxicity. A federal grand jury later indicted H.D. for causing the dispensing of controlled substances to T.H. without a legitimate medical purpose and not in the usual course of professional practice.

500. **The stimulant trinity.** Third, Walmart pharmacists repeatedly filled a similarly dangerous drug cocktail sometimes referred to as the "stimulant trinity" or "blackout trinity," consisting of (a) an opioid, (b) a benzodiazepine, and (c) a stimulant. The stimulant trinity is dangerous, given that the effects of the stimulant may lead the user to overdose on the opioid and/or the benzodiazepine in an effort to achieve the desired euphoria.

501. For example, for customer J.H., Walmart dispensed a stimulant trinity every month from January 2015 through July 2015, all based on prescriptions written by S.L. All components of the trinity combinations that Walmart provided to J.H. were dispensed either on the same day or within a few days of one another, and they were often accompanied by additional tablets of extended-release oxycodone 80mg (specifically, for the brand OxyContin). With only two exceptions, all of those pills were dispensed from the same Walmart pharmacy.

502. Another of S.L.'s patients, H.T., received so many opioids, benzodiazepines, stimulants, and sedatives from Walmart from April 2014 through June 2015 that H.T. could

make all three kinds of trinity combinations—classic, zolpidem, and stimulant—with them nearly every month. On multiple occasions, H.T. sought (and received) Schedule II drugs seven or more days early, further demonstrating the invalidity of the prescriptions.

503. On some occasions, pharmacists dispensed dangerous trinity combinations to individuals after another Walmart pharmacist had refused to do so. For example, on March 25, 2014, a pharmacist at Store 3370 in Palmetto, Florida, refused an Adderall 30mg prescription for A.L., written by M.M., whose pill-mill activity is described above. *See supra* ¶¶ 335-344. The pharmacist explained that the prescription for a stimulant was being refused given the combination of prescriptions A.L. was obtaining, observing that A.L. "receives multiple controlled substances that are uppers and downers (oxycodone, morphine, xanax, soma, and now adderall)" and noting, "This is an inappropriate combination." Nevertheless, about one month later, on April 30, 2014, another Walmart pharmacist, at Store 5420 in Kissimmee, Florida, filled A.L.'s prescriptions written by M.M. for a stimulant (amphetamine/dextroamphetamine combination 30mg), as well as a sedative (alprazolam 2mg) and a muscle relaxant (carisoprodol 350mg).

504. **The trinity plus.** Fourth, Walmart pharmacists repeatedly dispensed a drug cocktail consisting of (a) two or more different immediate-release opioids (including different strengths of the same opioid); (b) a benzodiazepine; and (c) either carisoprodol or zolpidem. This "trinity plus" combination creates many of the same risks of abuse or overdose as the other trinity combinations but, with the addition of another opioid, has an increased risk of abuse, overdose, or death.

505. Some pill-mill prescribers commonly prescribed this trinity-plus combination. For example, nearly every month from November 2014 through December 2015, Walmart filled

prescriptions for a patient of Oklahoma prescriber J.R. for 30 tablets of zolpidem 10mg, 60 to 90 tablets of alprazolam 2mg, at least 120 tablets of oxycodone 15mg or 30mg, and at least 120 tablets of a second opioid—oxycodone-acetaminophen 10/325mg. As explained above, *see supra* ¶ 483, J.R. voluntarily surrendered her medical license to resolve allegations regarding her improper prescribing.

506. In another example, a trinity-plus prescription was issued by H.D., a prescriber whose pill-mill prescribing practices are described above. *See supra* ¶¶ 290-302. The Texas Medical Board found that H.D. engaged in "non-therapeutic prescribing and overprescribing of opioids" for an individual, M.G. The Texas Medical Board cited several prescriptions written by H.D. and filled by Walmart Store 6350 for M.G., including prescriptions filled on March 29, 2013; May 3, 2013; May 28, 2013; and August 27, 2013, for a dangerous trinity cocktail—alprazolam 1mg; oxycodone 15mg; and zolpidem 10mg—plus extended-release morphine sulfate 15mg or 30mg.

507. Similarly, Walmart filled, on a monthly basis, the zolpidem trinity plus prescriptions for T.G. of Arkansas from April through December 2014. Specifically, each month Walmart dispensed two opioids—240 tablets of oxycodone 30mg and 240 tablets of hydromorphone 40mg, totaling 488 MME per day; 120 tablets of diazepam 10mg; and 30 tablets of zolpidem 10mg. These invalid prescriptions were written by prescriber H.T. of Missouri, for whom such cocktails were not uncommon. A Walmart pharmacist in Joplin, Missouri, later blanket refused to fill prescriptions written by H.T. because, among other things, she "routinely writes for a 'cocktail' of commonly abused drugs or combo that can cause medical complications" and she "writes for large doses of controlled substances."

508. All told, from June 2013 forward, Walmart pharmacists filled thousands of

prescriptions falling into the four trinity categories. The pharmacists filling these prescriptions, often revealing other red flags, did so knowing, at a minimum through willful blindness, that the prescriptions were invalid

(c) Red Flag Combination No. 3: Excessively repeated fills of high dosages of often-abused opioids

509. As trained pharmacists were aware, and as Walmart recognized in POM 1311 (2015), certain prescriptions presented obvious red flags if they were "for an unusually large quantity or high starting dose." Walmart pharmacists often reported in refusal-to-fill forms that prescriptions for high dosages were a red flag.

510. Nevertheless, for some individuals, Walmart pharmacists repeatedly filled prescriptions for extraordinarily high dosages of opioids. In fact, for numerous individuals, Walmart dispensed such high quantities of high-strength opioids that the *average* daily MME across the opioid prescriptions filled for each individual by Walmart exceeded 800 MME.

511. Many of these high-dose prescriptions involved drugs that were widely known to be abused, including oxycodone 30mg. Despite the well-known risk of abuse, Walmart pharmacists repeatedly filled prescriptions for 120 tablets of oxycodone 30mg for seven consecutive months or more, and in many instances did so for individuals who paid in cash. For example, for customer J.L. in Florida, Walmart pharmacists filled an average of 124 tablets per month of oxycodone 30mg for 42 consecutive months from February 2015 through July 2018.

512. For customer D.M., Walmart dispensed excessive quantities of not just one, but three potent opioids. Specifically, every month from December 2014 to September 2015, Walmart gave D.M. 30 fentanyl 100mcg/hr patches *plus* 450 methadone 10mg pills *plus* 328 to 480 oxycodone 30mg pills. The methadone alone was enough to give D.M. an average daily MME of 1,800, and yet the same Walmart store that dispensed those massive quantities of

methadone also gave D.M. fentanyl (an extremely potent opioid) and the highest strength of immediate-release oxycodone available.

513. From June 2013 forward, Walmart pharmacists filled numerous high-MME prescriptions. Many of these prescriptions presented additional red flags signaling diversion. The pharmacists filling these prescriptions, which often revealed other red flags, did so knowing, at a minimum through willful blindness, that the prescriptions were invalid.

(d) Red Flag Combination No. 4: Repeated early requests for fills of often-abused controlled substances

514. As trained pharmacists were aware, an individual's request to fill a controlled-substance prescription early was a red flag because it suggested that the individual was either taking a higher quantity than prescribed or diverting at least some of the pills to other individuals.

515. Because a prescription for a given controlled substance requires the dosage, quantity, and directions for use, *see* 21 C.F.R. § 1306.05(a), there is a specific date on which the supply of drugs dispensed pursuant to that prescription will be exhausted. For example, if a prescriber prescribes a drug of a particular dose, directs that it be taken six times per day, and prescribes a total of 180 tablets, the prescription authorizes a 30-day supply of drugs for the individual. If the individual follows the prescriber's directions, the 180 tablets will run out on the 30th day of taking the drugs.

516. Under 21 C.F.R. § 1306.12(a), "[t]he refilling of a prescription for a controlled substance listed in Schedule II is prohibited." As a result, a pharmacy may dispense Schedule II controlled substances only pursuant to a *new* prescription written for the patient by a prescriber; it may not refill the earlier prescription. In certain circumstances, prescribers may, on the same date, issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day

supply of a Schedule II controlled substance, but in doing so, the prescriber must provide "written instructions" on each prescription "indicating the earliest date on which a pharmacy may fill each prescription." 21 C.F.R. § 1306.12(b)(1)(ii).

517. Walmart recognized that early refills could signal diversion. The list of patient-related red flags in POM 1311 (2015) included an "[i]ndividual [who] routinely attempts to obtain an early refill on controlled substances." And in at least one communication, one of Walmart's compliance team members, B.N., indicated that when there was a pattern of early refill requests, the pattern may "indicate that the prescription is being used in a manner other than how the … drug was prescribed."

518. Furthermore, Walmart had a policy, POM 1318 (2011), that directly addressed filling prescriptions for controlled substances early. It recognized that "[p]harmacists are … tasked by regulatory agencies with monitoring for signs of misuse or abuse of medications, in particular controlled substances," and indicated that Walmart's pharmacy management software, Connexus, alerted pharmacists when requests were made to fill prescriptions more than 72 hours ahead of the next permitted fill date of a controlled-substance prescription.

519. Walmart filled prescriptions early for some individuals multiple times. These prescriptions included prescriptions known to be highly abused, such as oxycodone 30mg.

520. For example, from March 2013 to March 2017, Walmart pharmacists at Store 4926 in Columbus, Indiana, provided a single customer, M.B., with 25 early fills of oxycodone 30mg tablets of 120 tablets or more.

521. In addition, Walmart pharmacists filled prescriptions early when the individuals presented other red flags. Hundreds of these prescriptions were paid for in cash, and hundreds more were sold to patients who were from a state different from that of the prescriber and/or

pharmacy.

522. A pharmacist filling early a prescription that revealed additional red flags did so knowing, at a minimum through willful blindness, that the prescription was invalid.

(e) Other combinations of obvious red flags showing invalidity

523. In addition to the combinations of red flags discussed above, Walmart pharmacists filled prescriptions that had other combinations of red flags so obvious that, in filling them, the pharmacists knew of the prescriptions' invalidity.

524. A few examples are set forth below.

A.T. and J.R.: The months-old prescriptions

525. Walmart pharmacists in Florida filled prescriptions for A.T. and J.R. that were issued by pill-mill prescriber W.W., described above, *see supra* ¶¶ 426-435, despite a combination of obvious red flags showing that the prescriptions were invalid. Even if the Walmart pharmacists filling these prescriptions did not know about W.W.'s pill-mill practices, the red flags were so serious that, to fill them, the pharmacists knew, at a minimum through their willful blindness, that the prescriptions were invalid.

526. On November 15, 2013, J.R. and A.T. each presented to Store 1957 in Naples, Florida, two opioid prescriptions back-to-back, both written by W.W. The pharmacist refused to fill J.R.'s prescriptions for hydromorphone 2mg and MS Contin 30mg and A.T.'s prescriptions for MS Contin (morphine sulfate extended-release tablets) 60mg and Percocet (oxycodone-acetaminophen) 10/325mg, reporting that W.W.'s patients were "coming together in carloads," "stalking the pharmacy," and "excessively calling to find out of ciis [Schedule II medications] in stock."

527. J.R. and A.T. returned to Store 1957 three days later, and the pharmacy filled all four prescriptions that it had previously rejected.

528. Nearly five months later, in April 2014, A.T. presented Store 1957 with three old prescriptions issued by W.W. in November 2013. Despite the combination of obvious red flags showing the prescriptions' invalidity, the pharmacy filled them. In fact, from April 14, 2014, to April 30, 2014, Store 1957 dispensed 340 oxycodone-acetaminophen tablets to A.T.

B.N.: The prescriber's brother

529. A Walmart pharmacist in West Virginia filled a prescription issued for B.N. by pill-mill prescriber M.N.-A., described above, *see supra* ¶¶ 345-354, despite a combination of obvious red flags showing that the prescription was invalid. Even if the Walmart pharmacist who filled the prescription did not know about M.N.-A.'s pill-mill practices, the red flags were so serious that the pharmacist knew, at a minimum through willful blindness, that the prescription was invalid.

530. This prescription was later the subject of a guilty plea by M.N.-A. Written on July 15, 2014, the prescription was for 90 tablets of methadone 10mg and was for M.N.-A.'s brother, B.N. M.N.-A. did not document any medical justification for writing the methadone prescription. A week later, on July 22, 2014, Sam's Club Store 6457 in South Charleston filled the illegal methadone prescription for B.N., even though it was obvious that B.N. shared part of the same surname with M.N.-A., and even though the methadone prescription presented other unresolved red flags, including the high dosage. There are no notations on the prescription itself to indicate that the Walmart pharmacist who filled the prescription had resolved the red flags before filling it.

M.I.: Many high dosages, out-of-town, and cash

531. Walmart pharmacists in Florida repeatedly filled prescriptions issued to M.I. by prescriber F.T., a pill-mill prescriber described above. *See supra* ¶¶ 255-262. Even if the Walmart pharmacists filling these prescriptions did not know about F.T.'s pill-mill practices, the

red flags were so serious that, to fill them, the pharmacists knew, at a minimum through their willful blindness, that the prescriptions were invalid.

532. From July 2013 through July 2015, pharmacists at Walmart Store 3066, in Sarasota, Florida, filled approximately 59 controlled-substance prescriptions with obvious red flags issued by F.T. to M.I.

533. The prescriptions filled at Store 3066 for M.I. bore numerous obvious signs of invalidity, including the large dosages, dangerous combinations, and cash payments. As an example, on November 26, 2013, Store 3066 filled prescriptions for morphine sulfate 30mg (120 tablets), alprazolam (60 tablets), and orphenadrine ER 100mg (60 tablets), a muscle relaxant. Four days later, Store 3066 dispensed 30 tablets of morphine sulfate ER 60mg. M.I. paid for all four of these prescriptions in cash.

534. M.I.'s long history of such prescriptions was another red flag signaling invalidity. And M.I.'s prescriptions showed additional red flags, some of which were summarized by a pharmacist at Store 3066 on a rare occasion when the store refused to fill the prescription. On May 14, 2015, a pharmacist at Store 3066 refused to fill M.I.'s prescription for morphine sulfate 30mg, pointing to numerous unresolved red flags: "Prescriber is from out of area yet patient lives here, it does not make geographic sense that to drive to this doctor. This doctor has a history of writing for inappropriate drug therapies and inability to confirm valid patient prescriber relationship. Additionally, patient is filling #180 Morphine IR 30mg tablets each month and taking Oxycontin 80mg three times daily, I am concerned that this is a very high dose of opioids and risk of respiratory depression is further increased by use of benzodiazepines."

535. F.T.'s prescriptions issued to M.I. were, in fact, invalid, as the one pharmacist concluded. M.I. lived in Sarasota, Florida, nearly an hour from F.T.'s Tampa office and 30

minutes from the Punta Gorda office. F.T. performed a brief physical examination on M.I.'s first visit but did not physically examine her during any other appointments. She paid for F.T.'s appointments in cash. Over time, F.T. increased the amount of opioids prescribed to M.I. In 2015, M.I. was admitted to the emergency room, and the emergency room doctor told her that F.T. was "going to kill her with everything he was prescribing her." Later, M.I. admitted that she was addicted to opioids when she was F.T.'s patient.

536. M.I. had first tried filling her prescriptions from F.T. at a competing retail pharmacy, but she was told the pharmacy did not have the quantity or dosage in stock. M.I. tried another pharmacy, but she could not afford the prescriptions there since she was paying in cash. M.I. then began filling at Walmart.

537. For years, Walmart pharmacists filled prescriptions issued by F.I. for M.I. despite all the signs showing that they were invalid. For example, on May 15, 2015, Store 3066 dispensed to M.I. 180 tablets of morphine sulfate 30mg—the exact prescription a pharmacist at that store had refused to fill one day earlier—and 60 tablets of morphine sulfate ER 100mg.

c. Various factors contributed to Walmart pharmacists filling prescriptions despite their invalidity.

538. Walmart's policies and operations contributed to pharmacists' willingness to fill prescriptions they knew were invalid. At a minimum, these policies and procedures created a work environment and incentives that led to pharmacists' willful blindness to the invalidity of certain prescriptions. For example, as described in more detail above, *see supra* ¶¶ 139-144, Walmart pharmacists were subject to enormous pressure to fill prescriptions extremely quickly. Walmart pharmacists pointed not only to these time pressures, but also to business incentives, staffing shortages, and other factors at Walmart that made it difficult for them to refuse to fill an invalid prescription.

539. Walmart pharmacists reported that they felt pressure to fill a large volume of prescriptions, even if that meant not resolving red flags. For example, a Walmart pharmacist in South Carolina explained that taking the time to validate out-of-state prescriptions would "negatively impact customer service, wait times, and hence directly our business metrics." A former pharmacist at a Walmart store in Orlando, Florida, reported that the pharmacists often did not check the prescription monitoring program database because Walmart prioritized sales and customer satisfaction over safety. A pharmacy manager at a Walmart store in Missouri explained that there was nothing he could do about a problem prescriber because volume at his store was "already down" and addressing the issue would interfere with "sales goals."

540. Walmart pharmacists also complained that Walmart's restrictions dissuaded them from refusing to fill invalid prescriptions. As explained above, *see supra* ¶¶ 215, 219, pharmacists identified, as a factor that led them to fill such prescriptions, the compliance team's prohibition on blanket refusals to fill. For example, a pharmacist at Store 4557 in Las Vegas, Nevada, observed that the pharmacy was continuing to fill prescriptions issued by certain doctors who it knew were "shady," so long as the individual was a current patient of the doctor. The pharmacist explained that the pharmacy took this approach because it knew that, under Walmart policy, "we can't blanket refuse certain doctors."

541. Other Walmart pharmacists filled invalid prescriptions based on concerns that Walmart would disagree with their refusal to fill such prescriptions. For example, in 2015, a Walmart pharmacist at Store 36 in Paragould, Arkansas, complained that "his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions," and "expressed concerns that his leadership would not support his refusing to fill any 'legitimate' (written by a Dr) prescriptions." And the field supervisor for that store expressed concern that

"sending customers away" would "impact the sales figures for the store and [the field supervisor] was very insistent that the store needs to fill every available prescription."

542. Other Walmart pharmacists filled invalid prescriptions because they believed that they were not allowed to refuse to fill them. For example, at Store 742 in Kingsport, Tennessee, Walmart's second-highest pharmacy in dispensing buprenorphine, which is a Schedule III opioid, buprenorphine prescriptions were coming from three doctors at the same clinic and were being paid for in cash at a rate five times higher than that for other prescriptions. When the compliance team flagged the buprenorphine orders for the regional director, the regional director explained to B.N., "They all had concerns but didn't know their choices."

543. Another Walmart pharmacist, at Store 2967 in Fort Wright, Kentucky, indicated that the pharmacy was filling invalid prescriptions. The pharmacist reported that the pharmacy "is in a 'really bad area' for prescription drug abuse" and was seeing prescriptions from out-of-state doctors with patients paying in cash. But the pharmacist explained that the store essentially did not refuse to fill prescriptions: they "don't refuse to fill a prescription unless the patient is trying to get a refill too soon."

544. In sum, in the various ways outlined in this section and for the reasons explained above, Walmart's pharmacists dispensed thousands of prescriptions that they knew were invalid. Each time they did so, they violated their dispensing obligations under 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a), with conduct for which Walmart is liable.

C. Walmart's pharmacists repeatedly violated their obligations established by 21 U.S.C. § 829 and 21 C.F.R. § 1306.06 to follow fundamental professional practice standards when filling controlled-substance prescriptions.

545. It has long been recognized in the professional field of pharmacy that a pharmacist presented with a controlled-substance prescription has to take certain fundamental

steps to review the prescription. Pharmacists who do not take such steps fail to follow the usual course of professional practice. During the Dispensing Violations Period, Walmart pharmacists repeatedly failed to take these steps when filling controlled-substance prescriptions. As a result, they failed to properly dispense the controlled substances in the manner permitted by the Controlled Substances Act, *see* 21 U.S.C. § 829, and its implementing regulations, *see* 21 C.F.R. § 1306.06.

546. As discussed above, *see supra* ¶¶ 62-68, the CSA and its regulations permit pharmacists to "dispense" controlled substances pursuant to prescriptions, but only if the pharmacist follows the usual "course of professional practice."

547. As discussed above, *see supra* ¶¶ 69-76, the basic professional obligations of pharmacists require a pharmacist, when presented with a controlled-substance prescription bearing a red flag, to—as part of the usual course of professional pharmacy practice—take three basic steps: (a) identify the red flag, (b) investigate and resolve the red flag or refuse to fill the prescription, and (c) if the red flag is resolved, document the resolution. Walmart's own policies reflected these professional obligations. POM 1311 (2015) identified numerous red flags and stated that, before a pharmacist fills a controlled-substance prescription with any of these red flags, the red flags "should be evaluated, resolved, and documented."

548. These basic professional obligations apply when a pharmacist fills any controlled-substance prescription showing a red flag, regardless of whether the prescription is valid or not. Even if a prescription turns out to be valid, a failure to take these basic steps violates the usual course of professional practice for pharmacists.

549. Walmart pharmacists frequently did not take these required steps when presented with controlled-substance prescriptions bearing red flags. They did not take such steps as a

result of the factors set forth above, including high volumes of customers, staffing shortages, and corporate incentives and pressures to fill prescriptions quickly. *See supra* Part II.A.8. As set forth above, *see supra* ¶¶ 539-541, pharmacists reported that Walmart's "volume/staffing structure doesn't allow time for individual evaluation of prescriptions," that taking the time to validate out-of-state prescriptions would "negatively impact customer service, wait times and hence directly our business metrics," and that Walmart's prioritization of sales and customer satisfaction over safety led pharmacists not to check the prescription monitoring program database. As one pharmacist explained, high volumes of patients made it difficult to take the basic steps necessary to evaluate prescriptions raising red flags "when we receive at least 50 Rx for same medicine from same Dr and we are very busy."

550. On some occasions, Walmart pharmacists failed to investigate red flags based on their understandings of Walmart's policy. For example, in October 2015, pharmacists at Store 1728 in Anderson, Indiana, explained to Walmart's compliance team that, based on the pharmacists' understanding of Walmart's policy, they had not been contacting prescribers about hydrocodone prescriptions, even though the pharmacy had routinely been filling large prescriptions for hydrocodone. In another example, a Walmart Market Health and Wellness Director for Northern California explained, in connection with a visit in August 2017 to Store 1575 in Oroville, California, that the pharmacists there had an understanding that Walmart policy did not permit checking identification and thus were not checking customers' identifications for controlled-substance prescriptions, even when red flags were present, including customers attempting to pick up controlled-substance prescriptions that were not theirs.

551. Customers themselves observed on occasion that Walmart pharmacists did not seek to resolve obvious red flags. For example, R.F., a customer, stated that despite numerous

red flags, including that he drove considerable distances across North Carolina to get heavy doses of opioids and almost always bought his opioids from Walmart with cash, the Walmart pharmacist on duty never asked R.F. any questions about his prescriptions and never contacted his doctor to verify them.

552. In another example, Walmart filled over 100 controlled-substance prescriptions for customer A.D. in Colorado without checking and resolving red flags. From January 2013 until February 2016, it dispensed massive quantities of opioids and benzodiazepines to A.D. As A.D. later admitted, she was addicted to the opioids, but Walmart pharmacists always filled her prescriptions without asking her any questions. She also did not recall Walmart contacting her prescriber to discuss her prescriptions.

553. In another example, Walmart dispensed over 140 controlled-substance prescriptions to customer M.H. in Colorado without checking and resolving red flags. Walmart dispensed to M.H. large quantities of opioids, benzodiazepines, and sedatives from at least January 2013 through March 2016. M.H. was addicted to opioids and paid for her prescriptions in cash. But M.H. did not recall any Walmart pharmacists ever calling her prescriber's office to ask questions about her prescriptions, and Walmart never refused to fill any of her prescriptions.

554. Walmart's documentation further indicates that its pharmacists repeatedly failed to adequately identify and resolve red flags. In POM 1311 (2015), Walmart instructed its pharmacists to make notations in Connexus if they looked into red flags and resolved them. For some prescriptions bearing obvious red flags, Walmart pharmacists made notations that indicate that they did identify the red flags but did not adequately resolve them.

555. As set forth above, *see supra* Part II.B.2.c, in many instances Walmart pharmacists filled controlled-substance prescriptions showing a combination of obvious red flags

and there is reason to believe the pharmacist did not resolve the red flags before filling the prescription. For some prescriptions bearing obvious red flags, the Walmart pharmacists who filled the prescriptions made no notations at all indicating that they took any steps to resolve the red flags before filling the prescriptions. For example, a Walmart pharmacist in West Virginia filled a prescription issued by pill-mill prescriber M.N.-A. despite a combination of obvious red flags showing that the prescription was invalid, including that the customer shared part of the prescriber's surname and would receive an unusually high dosage of methadone. In filling that prescription, the pharmacist made no notations on the prescription itself indicating that red flags had been resolved.

556. In sum, Walmart pharmacists presented with controlled-substance prescriptions repeatedly failed to comply with three basic professional obligations—to identify red flags, to take steps adequate to resolve them or refuse to fill the prescription, and to document the resolution. In each instance where its pharmacists violated those professional obligations, Walmart failed to comply with 21 U.S.C. § 829 and 21 C.F.R. § 1306.06.

III. WALMART, AS A DISTRIBUTOR, VIOLATED THE CSA.

557. As alleged above, Walmart acted as a distributor of controlled substances, delivering millions of shipments to Walmart-branded and Sam's Club-branded pharmacies throughout the country.

558. The Attorney General, by regulation, has long required distributors to design and operate a system to detect suspicious orders of controlled substances, and to report those orders to DEA. *See* 21 C.F.R. § 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered

by the registrant."). Suspicious orders "include," but are not limited to, orders that are unusual in size, pattern, or frequency. *Id.*

559. As explained below, Walmart failed to comply with its obligation under 21 C.F.R. § 1301.74(b) and did not report an extraordinary number of suspicious orders. It also violated the CSA by failing to design and operate a system to report suspicious orders to DEA.

A. Walmart had a wealth of information and data about dispensing patterns and its own pharmacies' orders such that it could readily have designed a system to adequately report suspicious orders.

560. Walmart operated at least six distribution centers ("DCs") that distributed controlled substances to its pharmacies in the United States: Bentonville, Arkansas ("DC 6045"); Rogers, Arkansas ("DC 6001"); Tifton, Georgia ("DC 6013"); Crawfordsville, Indiana ("DC 6028"); Hanford, California ("DC 6032"); and Williamsport, Maryland ("DC 6046"). Of these distribution centers, only Bentonville ("DC 6045") distributed Schedule II controlled substances.

561. Throughout the period from 2012 to 2018, Walmart was the largest self-distributor in the country for oxycodone, hydromorphone, and hydrocodone in terms of both dosage units and grams.

562. Because Walmart acted as its own distributor, it had extensive data and other significant information that independent distributors would not ordinarily have.

563. In particular, Walmart had a wealth of dispensing information that gave it the ability to investigate the circumstances underlying orders for controlled substances. Walmart had data about individuals who filled controlled-substance prescriptions at its pharmacies, the identities of the medical providers who were prescribing controlled substances for those individuals, and reports from its own pharmacists raising concerns.

564. Walmart had additional data and other information that could signal that an order was suspicious, or could be used in evaluating a suspicious order, including but not limited to the following:

a. instances in which a pharmacist had refused to fill prescriptions written by particular prescribers;

b. knowledge of pill-mill prescribers whose patients filled prescriptions at Walmart pharmacies and the specific controlled substances that they unlawfully prescribed to patients;

c. knowledge of Walmart's own pharmacists, pharmacy managers, and market directors;

d. the distance between prescribers, patients, and pharmacies;

e. information concerning patients who paid cash for controlled-substance prescriptions;

f. drug diversion trends; and

g. previous DEA Form 106 (Theft and Loss) filings.

565. Walmart also had distribution-related data and other information, including but not limited to the following:

a. the number of bottles of controlled substances that each of its pharmacies had already ordered in any given week;

b. historical order quantities and patterns;

c. order and shipment history for orders that Walmart pharmacies placed with independent distributors (e.g., McKesson Corporation and AmerisourceBergen Corporation ("AmerisourceBergen")), including reports warning when a

pharmacy was nearing an independent distributor's threshold and information about instances when an independent distributor had refused to ship the order;

d. orders that had been previously flagged for its pharmacies using order-size thresholds;

e. analytics concerning each pharmacy's ratio of controlled-substance purchases to non-controlled-substance purchases;

f. previous suspicious-order reports for its pharmacies; and

g. prior and current suspicious order monitoring ("SOM") remediation plans, discussed below, for its pharmacies.

566. Walmart had the capability to use sophisticated data analytics to enhance and optimize its pharmacy operations. Walmart has emphasized that it relies on "big data" in its pharmacy operations to "enhance, customize and optimize the shopping experience" and "to make Walmart pharmacies more efficient," namely by using the data to "help[] the pharmacy with staff scheduling and to reduce the amount of time it takes a prescription to be filled." https://corporate.walmart.com/newsroom/innovation/20170807/5-ways-walmart-uses-big-data-to-help-customers (last visited Dec. 18, 2020).

567. Although Walmart had the ability to use all this data and other information to flag and report suspicious orders, it chose not to do so.

568. In addition to unusual orders flagged by Walmart's order-size thresholds, Walmart's compliance team received information about other unusually large orders and unusual circumstances at certain of its pharmacies.

569. For instance, in December 2014, a Walmart pharmacy manager reported to B.N., Walmart's Director of Corporate Compliance, Health and Wellness, that Store 1480 in Randolph

County, Indiana, was dispensing a volume of Schedule II controlled substances that was disproportionate to that community's very small size: "The amount of Schedule II controls coming out of this pharmacy seems way way off base.… To give you an idea, we dispensed 37,000 hydrocodone tablets (all strengths) in the 30 day period from Oct. to November. This is just hydrocodone, once you factor in the oxycodone we're talking well into 40,000 schedule II pain tablets per month coming out of this pharmacy.… There is simply no way this many people in this community are in this much pain." The pharmacy manager further stated that "I do know there are warehouse controls that will only ship so much CS [controlled substances] but it would seem those limits are set pretty high as we do not run out of controls, despite our volume."

570. Moreover, certain corporate employees had access to dispensing and distribution data and, in some cases, these same employees controlled Walmart's policies and practices for both dispensing and distribution.

571. In September 2015, Walmart created a "Health and Wellness Controlled Substance Advisory Panel" to oversee "the Health and Wellness Division's Controlled Substance Compliance Program ('Program'), which addresses compliance with state and federal laws, regulations and standards of conduct related to controlled substance dispensing and distribution."

572. One member of the Controlled Substance Advisory Panel, M.J., was, at times, responsible for developing both dispensing and distribution policies and practices.

573. Among her many responsibilities, M.J. reviewed pill-mill prescribers as part of Walmart's prescriber review program, modified the refusal-to-fill policy and other policies related to dispensing, and handled dispensing data.

574. Additionally, M.J. oversaw Walmart's distribution compliance with respect to both high-level policy and day-to-day implementation of the SOM program. She was

responsible for executing Walmart's SOM policies and "developed [a] strategy for a much more comprehensive program than was initially developed." And for most of the Distribution Violations Period, M.J. was one of two people charged with determining which orders placed by Walmart pharmacies were suspicious and therefore had to be reported to DEA.

575. Although Walmart had all of this information and had employees with control over both its dispensing and distribution practices, these employees did not use this information and corporate knowledge for suspicious order monitoring.

B. For years, Walmart knew that its policies and procedures were causing it not to report many suspicious orders, but Walmart failed to fix these defects.

576. During the Distribution Violations Period, Walmart's SOM program contained significant defects that prevented Walmart from reporting at least hundreds of thousands of suspicious orders that its pharmacies placed with its distribution centers.

577. As explained below, numerous internal documents demonstrate that Walmart compliance personnel knew, throughout this period, of significant defects with its SOM program. And these same personnel knew that these defects were leading to underreporting suspicious orders.

578. For example, by mid-2014, Walmart officials recognized that Walmart was at risk of enforcement from DEA because it was not reporting suspicious orders as required by 21 C.F.R. § 1301.74(b). In an attachment to a June 12, 2014, email sent by M.J. (then Director of Compliance), Walmart considered modifying its SOM system "to help Walmart avoid DEA enforcement as a result of non-compliance with 21 CFR 1301.74(b)."

579. In the same June 12, 2014, email, Walmart attached a risk assessment in which it observed that its system for monitoring suspicious orders was an "existing risk" and "emerging risk" for which it had "no processes in place." Walmart's own assessment was that the risk that

its pharmacies would place suspicious orders with its own distribution centers was "likely," the second-highest of five levels on Walmart's scale of likelihood of risks.

580. During the Distribution Violations Period, Walmart's SOM program—including the systems, policies, and procedures that Walmart employed to monitor suspicious orders—changed and went through multiple iterations.

581. However, these changes were not sufficient to fix the known defects and meet Walmart's legal obligation under 21 C.F.R. § 1301.74(b) to report suspicious orders.

1. Prior to August 2015, Walmart had a rudimentary suspicious-order monitoring system that Walmart employees knew failed to report suspicious orders.

582. On or about December 27, 2007, DEA sent letters to all registered distributors of controlled substances, including Walmart, reminding them of their legal obligation under 21 C.F.R. § 1301.74(b) to detect and report suspicious orders to DEA.

583. In the December 27, 2007, letter, DEA advised distributors that failing to comply with their obligations could lead to great harm: "[A]ll registrants—manufacturers, distributors, pharmacies, and practitioners—share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

584. Nevertheless, prior to November 2010, Walmart had no written policies or procedures related to the identification or reporting of suspicious orders.

585. In November 2010, Walmart adopted Pharmacy Manual 21-402 ("Controlled Substance Monitoring"). This policy remained in place during the beginning of the Distribution Violations Period.

586. Pharmacy Manual 21-402 (November 2010) did not define "suspicious orders" or

state that Walmart was required to report suspicious orders to DEA.

587. By 2011 or 2012, Walmart instructed compliance team personnel to evaluate individual orders as they were placed and report any suspicious orders to DEA.

588. Walmart directed its personnel first to identify "orders of interest" from among all controlled-substance orders, and then to investigate those "orders of interest" to evaluate "the unusual characteristics of the order," which included unusual frequency, unusual size, and unusual pattern.

589. As detailed below, however, both steps of this system failed. The criteria Walmart adopted for flagging "orders of interest" in the first instance were plainly inadequate, allowing many suspicious orders to evade any scrutiny. And Walmart routinely failed to investigate orders that were flagged as "orders of interest" to ascertain whether they were suspicious, prioritizing expeditious distribution of controlled substances to meet its pharmacies' and pharmacists' demands over compliance with DEA regulations.

590. As a result of these defects, Walmart reported to DEA only a miniscule percentage of its pharmacies' suspicious orders.

a. Walmart knew it was failing to report orders of unusual frequency or pattern.

591. Despite the requirements in 21 C.F.R. § 1301.74(b) to report orders showing unusual frequency and unusual pattern, Walmart's SOM system focused exclusively on the size of orders. It contained no processes to flag or report orders with unusual frequency or unusual pattern.

592. During the Distribution Violations Period, most of Walmart's six distribution centers used a system called Reddwerks as their order fulfillment system. Reddwerks tracked orders placed by Walmart pharmacies, as well as shipments from Walmart distribution centers to

the pharmacies in fulfillment of those orders.

593. Although the Reddwerks system was not designed for monitoring suspicious orders, Walmart used it for that purpose. Specifically, Walmart used Reddwerks to set "order alerts"—sometimes known as "thresholds"—that would flag only orders over a certain quantity.

594. Walmart had an opportunity to design a system that would have flagged unusual ordering patterns. As early as February 2014, Walmart retained an outside consultant, Mu Sigma, to review its SOM program. Mu Sigma informed Walmart that it could revise its SOM program to detect Walmart pharmacies' unusual ordering patterns and combinations, which could indicate that a particular Walmart pharmacy was dispensing dangerous drug "cocktails."

595. Despite this independent evaluation of Walmart's SOM program from Mu Sigma, Walmart ignored its recommendations and did not revise it in any other way to flag unusual, dangerous patterns during the Distribution Violations Period.

596. Walmart knew that its SOM system was deficient in that it ignored pattern and frequency, in violation of the law. In an internal presentation from October 2014, just a few months after the July 2014 SOM policy had been put in place, Walmart recognized that Reddwerks "[f]lags only identify 'unusual size'." That deficiency remained uncorrected for years.

597. Because Walmart's system was not designed to flag orders for unusual frequency and unusual pattern, Walmart did not report any of these orders to DEA, in violation of the law.

b. Walmart knew it was failing to report some unusually large orders.

598. Despite Walmart's sole focus on order size, its monitoring still failed to flag significant numbers of orders of "unusual size." Other times, Walmart flagged unusually large orders but did not report them to DEA.

599. There were several different flaws in Walmart's approach to monitoring the size

of orders, as explained below.

i. Walmart knew that, in setting order-size thresholds and limits, it was disregarding differences among pharmacies and among controlled substances.

600. In approximately 2011 or 2012, Walmart's SOM program began using weekly size "thresholds" and "hard limits" for the quantity of controlled substances that each of its pharmacies could order from the six Walmart distribution centers.

601. An order that hit a "threshold" was supposed to trigger a temporary "hold" of that order for further evaluation.

602. A "hard limit" nominally served as the maximum amount that a pharmacy could order of a particular drug, but as explained below, Walmart sometimes ignored its own hard limits, allowing its pharmacies to order and receive quantities greater than the hard limit.

603. The thresholds and hard limits ignored significant differences between pharmacies. Walmart knew that its pharmacies varied significantly in many respects. For instance, some served sparsely populated rural communities, while others served suburban or urban communities with denser populations. Likewise, depending on location, Walmart pharmacies might face differing levels of competition from other retail chain pharmacies or independent pharmacies. Customer characteristics also differed in material ways, such as age and diagnoses, which affected the types and amounts of controlled substances each pharmacy needed to stock and dispense to meet legitimate customer demand.

604. Despite its knowledge of these variations among pharmacies, Walmart applied the same numeric thresholds to each of its pharmacies and did not tailor its order-size thresholds. Regardless of the attributes of the pharmacy placing an order, Walmart's SOM system uniformly flagged the following weekly order totals:

- Schedule II controlled substances that exceeded 20 bottles,

- Schedule III-V controlled substances that exceeded 50 bottles, and
- 30% above four-week average (if 11 bottles or greater).

605. Walmart understood that controlled-substance orders that triggered these thresholds, and thus were flagged by Walmart's SOM system, were "unusual." For instance, Walmart recognized that flagged orders greater than 50 bottles were "unusual orders." Answering the question of "How do you identify unusual orders (controls and non-controls)?," E.O., the General Manager of DC 6046 in Williamsport, Maryland, stated in a document dated October 18, 2013, that "DC6046 utilizes the Reddwerks screen to identify over 50 bottles."

606. In a document titled "Overview of SOM Project Progress," which was attached to a November 23, 2014, email from a senior manager of logistics to other compliance team members, Walmart acknowledged that thresholds for its pharmacies were set "regardless of store history."

607. In addition, Walmart had no rationale for its decision to set a 50-bottle threshold for Schedule III, IV, and V controlled substances. The "Overview of SOM Project Progress" stated that Walmart lacked any documentation showing why 50 bottles had been selected as a threshold for certain controlled substances.

608. Just as Walmart, by setting one-size-fits-all thresholds, failed to account for differences in pharmacies, Walmart also failed to account for differences in the schedule of controlled substances. This uniform threshold for all Schedule III, IV, and V controlled substances meant that a pharmacy could order the same amount—up to 50 bottles—of a highly addictive Schedule III narcotic as it could order of a Schedule V controlled substance with a lower potential for abuse.

609. As a result of Walmart's one-size-fits-all approach in setting thresholds and hard

limits, Walmart failed to report many unusually large orders.

ii. Walmart knew that it was routinely shipping, and not reporting, orders exceeding its hard limit for oxycodone 30mg.

610. Starting in or about July 2012, Walmart implemented a "hard limit" of 20 bottles of oxycodone 30mg per week, per pharmacy.

611. Oxycodone 30mg was the only controlled substance and only dosage strength for which Walmart imposed a "hard limit" on the number of bottles its pharmacies could order each week.

612. Despite this particular attention on this one drug formulation, Walmart frequently disregarded its own 20-bottle "hard limit" for oxycodone 30mg, a highly addictive Schedule II controlled substance.

613. Between June 2013 and July 2015, on at least 216 separate occasions, Walmart shipped to its pharmacies more than 20 bottles of oxycodone 30mg in one week.

614. This problem was concentrated in a handful of pharmacies. Approximately half of the orders where Walmart disregarded its own hard limit of 20 bottles of oxycodone 30mg went to only six pharmacies: Store 5350 in Salt Lake City, Utah; Store 1560 in Las Vegas, Nevada; Store 5697 in Milwaukee, Wisconsin; Store 2708 in Temecula, California; Store 130 in Muskogee, Oklahoma; and Store 5047 in Audubon, New Jersey.

615. For example, during a 12-week period in 2015, Store 130 in Muskogee, Oklahoma, received more than 20 bottles of oxycodone 30mg in 11 of those weeks, for a total of 248 bottles.

616. By way of another example, over a 14-week period in 2014, Walmart repeatedly shipped much more than 20 bottles of oxycodone 30mg to Store 5350 in Salt Lake City, Utah. Walmart ultimately shipped a total of 399 bottles to this pharmacy over these 14 weeks.

Moreover, during the broader time period of June 2013 through July 2015, on 41 separate occasions, Walmart sent weekly shipments totaling more than 20 bottles of oxycodone 30mg to Store 5350.

617. Despite repeatedly violating its own hard limit, Walmart did not report to DEA as suspicious any of the orders resulting in the shipments identified above.

iii. Walmart knew that its size thresholds failed to detect some unusually large orders because those thresholds were based on the number of bottles, not the number of dosage units.

618. Prior to August 2015, Walmart's size thresholds were based on the number of bottles, rather than on the number of dosage units included in each bottle.

619. Throughout this period, Walmart knew that setting thresholds based on bottle quantity rather than dosage-unit quantity presented a loophole for pharmacies to order excessive amounts of controlled substances.

620. In a memorandum drafted on or about October 11, 2013, E.O., the General Manager of DC 6046 in Williamsport, Maryland, pointed out that "several control … items have changed from a 100 count bottle to a 1000 count bottle," such that a pharmacy that had previously ordered 20 bottles of a controlled substance for a total of 2,000 dosage units was now able to order 20 bottles of the same controlled substance for a total of 20,000 dosage units. E.O. concluded that "[t]he system now should flag pills verses [sic] bottles."

621. In the "Overview of SOM Project Progress," Walmart knew of this deficiency, noting that "[m]onitoring level = 50 bottles (regardless of store history, *bottle size*, etc) or order amount >30% over rolling 4 week average." (Emphasis added.)

622. Because of this flaw, pharmacies could evade the bottle-based thresholds, obtaining more dosage units of controlled substances without scrutiny by ordering bottles containing more pills.

623. For example, in two shipments on December 12 and 13, 2013, Store 7259 in Georgetown, Kentucky, received a total of 10 bottles of oxycodone hydrochloride-acetaminophen 5/325mg, each containing 500 pills. Store 7259 thus received 5,000 dosage units in one week. Store 7259 could have obtained the same number of dosage units by ordering bottles containing only 100 pills per bottle, but then it would have ordered 50 bottles and exceeded the 20-bottle threshold. With Walmart ignoring dosage units and focusing only on bottle number, Store 7259 was able to receive 2.5 times as many pills while evading scrutiny—and potential reporting to DEA as a suspicious order—because it stayed below the 20-bottle threshold simply by ordering a larger bottle size.

624. In another instance, on February 26 and 27, 2014, Store 2156 in Middle Island, New York, received a total of nine bottles of oxycodone hydrochloride-acetaminophen 5/325mg, each containing 500 pills. Store 2156 thus received 4,500 dosage units in one week. If Store 2156 had ordered bottles containing only 100 pills per bottle, the pharmacy would have had to order 45 bottles to obtain the equivalent dosage units, which would have exceeded the 20-bottle threshold for evaluation of Schedule II controlled-substance orders. Instead, Store 2156 was able to receive more than two times as many pills while evading scrutiny—and potential reporting to DEA as a suspicious order—because it stayed below the 20-bottle threshold simply by ordering a larger bottle size.

625. Although Walmart knew as early as October 2013 that relying on order-size thresholds based on the number of bottles presented problems, Walmart delayed fixing this problem and did not implement order-size thresholds based on the number of dosage units until at least August 2015.

iv. Walmart knew that its size thresholds failed to detect some unusually large orders because its size thresholds did not focus on drug type and strength.

626. Another flaw in Walmart's size thresholds was that Walmart's SOM program did not aggregate and flag multiple orders placed by a pharmacy for the same drug and strength, if those orders were for products that had different National Drug Codes because they were made by different manufacturers. A National Drug Code ("NDC") is a unique, three-segment number which serves as a universal product identifier for drugs.

627. For example, in 2014, DC 6045 shipped several orders of oxycodone 30mg that were made by different manufactures and were unusual when aggregated to Store 5350 in Salt Lake City, Utah. Over the course of one week from November 25, 2014, to November 28, 2014, Store 5350 received 16 bottles of oxycodone 30mg (NDC 10702000901) and 19 bottles of oxycodone 30mg (NDC 228287911), but neither weekly shipment total—based on NDC alone—was flagged as exceeding 20 bottles. Each order exceeding the weekly hard limit of 20 bottles of oxycodone 30mg should have been flagged and reported to DEA as suspicious, but Store 5350 evaded the 20-bottle hard limit because the NDCs differed, allowing Store 5350 to receive 35 bottles of oxycodone 30mg in one week, almost twice the hard limit because of this loophole.

628. In another example, Store 2837 in Las Vegas, Nevada, received shipments of 12 bottles of oxycodone 30mg (NDC 10702000901) and 18 bottles of oxycodone 30mg (NDC 228287911) from DC 6045 on January 8, 2014. This weekly total of 30 bottles of oxycodone 30mg exceeded the 20-bottle hard limit, but was not flagged and reported to DEA as suspicious because Walmart failed to account for differing NDCs for the same drug strength.

629. Walmart's failure to close this NDC loophole enabled the oxycodone 30mg hard limit of 20 bottles to be exceeded at least 146 times between June 26, 2013, and July 31, 2015.

630. This problem of not evaluating the orders in the aggregate was not limited to

orders of oxycodone 30mg but extended to other Schedule II controlled substances. Because Walmart did not monitor Schedule II orders of the same drug and strength with different NDCs, Walmart's SOM system failed to flag at least 1,500 weekly shipments of other Schedule II controlled substances with a combined weekly total above 20 bottles for further evaluation.

v. When Walmart flagged orders of unusual size, it often "cut" or reduced the size of the orders, but failed to report them to DEA, despite knowing that this practice was unlawful.

631. Walmart also avoided reporting suspicious orders by "cutting," i.e. reducing the size of, orders that would otherwise raise concerns, down to a size Walmart considered acceptable. Specifically, when Walmart received an order from one of its pharmacies above the threshold of 20 bottles for a Schedule II controlled substance, or 50 bottles for a Schedule III, IV or V controlled substance, Walmart often "cut" that order down to 20 or 50 bottles, respectively.

632. Many compliance personnel at Walmart knew about the common practice of cutting suspicious orders because they received daily reports showing which orders had been "cut" or reduced in size. In an email dated September 27, 2012, G.C., a Senior Director for Health and Wellness, stated that the "warehouse would supply to AP, compliance and operations each day a report that highlighted any DC orders cut for oxycodone 30mg orders."

633. In an email dated October 14, 2013, J.A., Operations Manager at DC 6045, described the process that Walmart distribution centers used to determine whether to cut an order: "Once we identify an unusual order, we contact the Rx manager to find out if the amount requested is really needed or an ordering mistake. If needed, what is the reason for the increase. Depending on the answers we involve other people from the Market Manager to HO H&W Managers. If needed, the order is cut to a more normal ordering amount." In short, if the pharmacy intended to make an unusual order, the DC would cut the order to make it appear usual.

634. For instance, on October 16, 2014, J.A., Operations Manager at DC 6045, circulated a report to other Walmart compliance personnel, including M.J., showing several orders greater than 50 bottles that had been "cut" down to 50 bottles, shipped out to pharmacies the prior day, and not reported to DEA:

Date	Store	NDC	Description	Item Pack Quantity	Ordered	Sent
10/15/2014	1783	603388721	HYD/BIT/ACET 10/325	100	63	50
10/15/2014	5133	406012501	HYDRO/APAP 10/325MG	100	82	50
10/15/2014	1575	406012501	HYDRO/APAP 10/325MG	100	76	50
10/15/2014	1951	406012501	HYDRO/APAP 10/325MG	100	63	50

635. After Walmart set the 20-bottle hard limit for oxycodone 30mg orders in or about July 2012, the company's policy was that oxycodone 30mg orders exceeding the 20-bottle weekly limit were to be flagged and "cut" down so that the pharmacy would receive no more than 20 bottles.

636. In an October 14, 2013, email, J.A. stated that DC 6045—which was the only Walmart distribution center that distributed oxycodone 30mg—had a "standing" cut for oxycodone 30mg and that "[a]ny order over 20 bottles of this item is cut back to 20 bottles."

637. Although Walmart cut these orders and shipped the reduced (but still substantial) quantities of controlled substances to its pharmacies, Walmart did not report these unusually large orders to DEA.

638. This practice of cutting orders was not limited to orders that exceeded the 50-bottle threshold or 20-bottle hard limit. Walmart personnel would sometimes manually cut orders that had been flagged for exceeding the four-week average by greater than 30 percent, reducing these orders down to the four-week average. This was not an automatic cut performed by Walmart's system, but an affirmative decision made by Walmart personnel. These too were never reported to DEA.

639. Walmart's practice of cutting these unusually large orders and shipping the reduced portion without reporting the original large orders to DEA disguised the large quantities that its pharmacies repeatedly ordered.

640. Worse still, Walmart knew that its practice of shipping "cut" orders without reporting the orders to DEA violated DEA regulations.

641. For example, in a February 2015 meeting, DEA diversion investigators informed Walmart that Walmart's practice of receiving an order, reducing the quantity of the order, and shipping that reduced quantity without reporting the order as suspicious to DEA violated 21 C.F.R. § 1301.74(b).

642. Despite this knowledge, Walmart continued to unlawfully cut and ship orders without reporting them to DEA through at least November 29, 2017.

vi. Walmart knew it was ignoring shipments of controlled substances that its pharmacies were receiving from independent distributors.

643. Walmart recognized and knew that the SOM program had an additional, critical shortcoming: Walmart-branded pharmacies and Sam's Club-branded pharmacies ordered and received at least hundreds of thousands of shipments of controlled substances from McKesson and AmerisourceBergen, respectively, but Walmart did not factor in these shipments from independent distributors when considering whether the pharmacies had exceeded order-size thresholds and hard limits.

644. During the Distribution Violations Period, Walmart-branded pharmacies generally first placed all of their orders with Walmart's own distribution centers. Walmart-branded pharmacies generally received controlled substances from McKesson when Walmart's distribution centers could not fulfill the order.

645. McKesson, as a back-up supplier for Walmart-branded pharmacies, shipped at

least hundreds of thousands of controlled-substance orders to Walmart-branded pharmacies from June 2013 through July 2015.

646. AmerisourceBergen was the primary distributor for Sam's Club-branded pharmacies, and Walmart was a back-up supplier. As the primary distributor, AmerisourceBergen shipped at least hundreds of thousands of controlled-substance orders to Sam's Club-branded pharmacies from June 2013 through July 2015.

647. Walmart recognized that its SOM system was greatly flawed in that it failed to account for these independent distributors' shipments to its pharmacies. In an October 2014 internal presentation assessing the efficacy of its SOM system, Walmart noted that "McKesson orders are not considered in evaluation." Likewise, the "Overview of SOM Project Progress" attached to a November 23, 2014, email stated that Walmart had "[n]o process for including McKesson orders in evaluation."

648. Because of failures to account for orders with independent distributors, between June 2013 and July 2015, Walmart unlawfully failed to report to DEA significant numbers of its pharmacies' unusually large orders.

vii. Walmart attributed unusually large orders to "errors" to avoid reporting them as suspicious orders.

649. Walmart made up other reasons for not reporting unusually large orders to DEA. In particular, Walmart began classifying unusually large orders as "errors" in order to justify rejecting the order or reducing the size of the order, even when there was no basis for thinking the pharmacies had intended to order a smaller quantity.

650. In an email dated August 27, 2014, K.S., Senior Manager for Logistics, advised that "'[c]utting' an order should *only* be an option if the order is an error (eg store intended to order 10 bottles, ordered 100)." (Emphasis added.)

651. Although Walmart was aware that it should limit "cutting" orders to true "errors," J.A., the operations manager for DC 6045, stretched the meaning of "error" so broadly that it would conceal all sorts of suspicious activity.

652. In an internal email dated November 5, 2014, concerning the use of "error" as a reason code for cutting orders, J.A. wrote, "Many things could be considered an 'error' other than just mis-keying an order. Such as, due to the change of Hydro to a CII some pharmacist[s] feel the need to stock up. The company feels 50 bottles is enough and pharmacist shouldn't stock up, thus an error in decision making. And many other reasons not confined to mis-keying." (On October 6, 2014, hydrocodone was reclassified from a Schedule III controlled substance to a Schedule II controlled substance, which reflected DEA's concern regarding the abuse and diversion potential of hydrocodone.)

653. Walmart thus expanded its definition of "error" beyond its pharmacies' unintentional mistakes to include their deliberate placement of unusually large orders. This overly expansive definition of "error" caused Walmart to fail to report suspicious orders to DEA.

c. Walmart knew of, but ignored, specific signs of suspicious ordering at its own pharmacies

654. In addition to failing to report orders of unusual size, frequency, or pattern, Walmart's SOM program also ignored signs that suspicious ordering was occurring at certain pharmacies.

655. As noted above, 21 C.F.R. § 1301.74(b) defines suspicious orders as including orders that are suspicious for reasons other than unusual size, unusual frequency, or deviating from the normal pattern. Likewise, Walmart's own policies stated that suspicious orders were not limited to only orders of unusual size, pattern, or frequency.

656. Walmart has emphasized that its SOM personnel knew its customer because

Walmart's only pharmacy customer was itself. As mentioned above, it had a wealth of dispensing information to investigate the circumstances underlying orders, data about people who filled prescriptions at its pharmacies, and information about medical providers who prescribed controlled substances for those people.

657. Walmart's SOM program also recognized that properly evaluating whether an order was suspicious often required it to learn information from its pharmacies, including whether there were signs of diversion at its pharmacies. For instance, Walmart recognized that SOM evaluation included asking its pharmacists whether customers paid in cash, whether multiple customers came to their pharmacy at the same time with controlled-substance prescriptions written by the same prescriber, whether prescribers were writing for large quantities of controlled substances or the same prescription for most patients, whether prescribers were prescribing within the scope of their medical practice, and whether the prescribers' practices were near or far from the pharmacy.

658. Walmart's compliance personnel repeatedly learned of signs of suspicious and troubling circumstances pertaining to these very factors. Pharmacists reported in detail a wide variety of grave concerns about pill-mill prescribers; large groups of people descending on a single pharmacy and presenting the same prescription from the same prescriber; customers traveling great distances to visit a prescriber's office or fill prescriptions at Walmart (or both); several competitor pharmacies no longer filling any prescriptions written by certain prescribers; customers who were high while presenting prescriptions from known pill-mill prescribers; illegal diversion occurring inside Walmart's stores; and other extraordinary information suggesting prescriptions would be diverted. All of these warnings raised suspicion about those stores' controlled-substance orders.

659. Some Walmart compliance personnel who received and reviewed these troubling reports of specific signs of suspicious ordering also had responsibilities within Walmart's SOM program and were responsible for reporting suspicious orders to DEA.

660. Nevertheless, Walmart's compliance team ignored the evidence that orders placed by certain pharmacies with these indications of diversion were suspicious.

661. The very Walmart stores that submitted those warnings, as well as other Walmart stores, continued to fill prescriptions for those prescribers and patients and submitted orders to Walmart for the controlled substances to fill those prescriptions. Despite knowing about all of these warnings of diversion and suspicious circumstances from its own pharmacists, Walmart failed to report those orders as suspicious, thereby fueling the opioid epidemic.

d. Walmart knew that SOM program personnel were not adequately staffed and trained and that it shipped flagged orders before personnel could examine them.

662. During the Distribution Violations Period, Walmart was the largest private employer in the United States. For the fiscal year ending January 2015, Walmart employed 2.2 million associates worldwide, with approximately 1.4 million domestic employees.

663. Yet during this period, Walmart failed to devote sufficient personnel to operate its SOM program. Instead, Walmart was woefully understaffed for reviewing flagged orders from its 5,000 pharmacies and determining which of those orders were suspicious and, therefore, had to be reported to DEA.

664. For at least part of the time from June 2013 through July 2015, compliance personnel working in Walmart's home office were not involved in Walmart's suspicious-order monitoring program. K.S., a Senior Manager for Logistics, stated that "any decisions that needed to be made were being left to the distribution center…."

665. Walmart recognized this arrangement as inadequate and, in the "Overview of SOM Project Progress" attached to a November 23, 2014, email, listed several problems associated with Walmart's failure to involve home office compliance personnel in monitoring suspicious orders, including the following:

- "Inconsistent application of monitoring standards by associate across DC facilities;"
- "No consistent training for associates;"
- "No dedicated [Home Office] resource;" and
- "SOM policy only included DC associate responsibilities – no [Home Office] involvement or cross-functional collaboration."

666. Of particular concern was that Walmart failed to devote sufficient staff to monitoring orders of Schedule II controlled substances, which were the most dangerous controlled substances that Walmart distributed. All Schedule II controlled substances distributed by Walmart were distributed via DC 6045 in Bentonville, Arkansas. DC 6045 filled Schedule II orders itself, and it served as the intermediary between Walmart's pharmacies and the independent distributors when DC 6045 could not fill Schedule II orders on its own. At one point, there were only three employees at DC 6045 to review and evaluate hundreds of orders for Schedule II controlled substances that Walmart's own thresholds had flagged each day (and many more after hydrocodone was reclassified as a Schedule II drug effective October 6, 2014).

667. Walmart also did not allow its staff adequate time to examine flagged orders for Schedule II drugs placed with DC 6045. Although Walmart policy called for a temporary "hold" to evaluate orders that had tripped the company's thresholds, that "hold" was often overridden in favor of expeditious shipping to satisfy its pharmacies. At least at one point in time, if DC 6045

flagged orders exceeding 50 bottles but did not receive an instruction by 3:00 p.m. the same day as to whether the order was suspicious or appropriate for shipment, the distribution center shipped the unusually large order without reporting it to DEA.

668. At other distribution centers, Walmart similarly failed to provide its staff with the ability to evaluate the stream of orders from its pharmacies.

669. For example, at DC 6046 in Williamsport, Maryland, Walmart refused to devote adequate resources and personnel to properly evaluating orders that Walmart's SOM system had flagged for evaluation. As a result, it chose not to review every flagged order. In a memorandum circulated on or about October 11, 2013, E.O., an operations manager at DC 6046, stated that there were "too many orders to review each line [of Reddwerks orders alerts] in detail."

670. A year later, the problem had not been fixed. An internal presentation from October 2014 recognized that "[a]ll flags must be cleared before production on any items can begin, *so there is limited time for evaluation*." (Emphasis added.)

671. Walmart also failed to provide consistent, adequate training to the employees responsible for suspicious-order monitoring functions.

672. First, Walmart assigned SOM functions such as flagging, rejecting, and reporting suspicious orders, approving orders in excess of a threshold, and cutting orders to or below thresholds, to distribution center personnel who Walmart knew had limited or no prior experience with suspicious order monitoring or even with regulatory compliance of any kind.

673. Second, Walmart failed to provide these employees with training specific to monitoring suspicious orders of controlled substances, including appropriate training regarding drug diversion trends and the opioid epidemic. Walmart provided its staff with no training

program, training materials, or written policies, procedures, or criteria specific to suspicious order monitoring.

674. For example, J.A., the operations manager at DC 6045, possessed neither adequate experience nor training when he was charged with determining which Schedule II orders were suspicious. Walmart provided J.A. with no formal training and no written policies or procedures specific to suspicious order monitoring. Instead, J.A. relied on on-the-job learning as he was working with Schedule II drugs and "just looking at orders and just, you know, if something looked unusual, then that's what I looked at."

e. Walmart flagged unusual orders but then routinely failed to report flagged orders that Walmart was unable to clear through investigation.

675. Throughout this time period, Walmart set the following thresholds to flag unusually large orders for investigation: more than 20 bottles for Schedule II controlled substances, more than 50 bottles for Schedule III, IV, and V controlled substances, and order amounts that were 30% above the four-week average.

676. Walmart's policy required it to hold and evaluate all orders flagged by its SOM system, which Walmart referred to as "orders of interest." Pharmacy Manual 21-402 (July 2014) noted specifically that orders of interest "warrant[ed] follow-up evaluation to determine whether … [they are] suspicious." Consistent with the manual, compliance personnel knew of this requirement. K.S., a Senior Manager for Logistics, stated in an August 27, 2014, email, "Our obligation is to monitor all orders, *investigate 'orders of interest' (potentially 'suspicious' orders), hold any 'order of interest' until/unless the order is investigated and cleared* and report any 'suspicious' orders to DEA." (Emphasis added.)

677. Despite this clear policy, Walmart routinely failed to investigate thousands of flagged orders and report those orders to DEA.

678. For example, Walmart generated an internal report referred to as an "Over 20 report," which flagged all orders for Schedule II controlled substances that were greater than 20 bottles. Walmart referred to orders of more than 20 bottles of Schedule II controlled substances as "orders of interest" that warranted additional evaluation.

679. According to a February 2014 email from J.O., a Walmart Global Investigator, this "Over 20 CII Report" was "created by Warehouse for stores who have ordered what is deemed an 'excessive amount' of a CII Drug, particular attention is paid to Oxycodone Drugs." In the same email, J.O. stated that the report was to "monitor the amounts processed through a store so we don't let dispenses [sic] get out of hand, drawing the attention of the DEA to our stores."

680. But in many cases, no Walmart personnel at any level completed any investigation of these "Over 20" orders of powerful Schedule II controlled substances.

681. Walmart has admitted that it shipped all Schedule II orders of 21 to 50 bottles that its pharmacies placed—without conducting any meaningful investigation into those orders, and sometimes conducting no investigation at all.

682. From June 26, 2013, to July 31, 2015, Walmart shipped to its pharmacies at least 66,000 Schedule II orders in which the weekly totals ranged from 21 to 50 bottles. Walmart failed to file suspicious-order reports with DEA on nearly all of these orders.

683. In addition, one of Walmart's distribution centers—DC 6001 in Rogers, Arkansas—routinely shipped orders it had flagged for review, without reviewing them.

684. For at least part of the Distribution Violations Period, DC 6001 did not use Reddwerks to identify suspicious orders but, instead, used a system called KNAPP.

685. KNAPP was an order fulfillment system, but it had very limited ability to flag

unusual orders of controlled substances.

686. Under the KNAPP system, once an order was "flagged" by DC 6001 for further evaluation, the system could not "hold" that specific order while the order was scrutinized to determine whether the suspicion could be dispelled. Instead, due to limitations of the KNAPP system, if DC 6001 held a pharmacy's order for further evaluation, then all the other orders would also be held and not shipped.

687. In an email dated August 25, 2014, K.S., a Senior Manager for Logistics, noted that some Walmart employees were "uncomfortable with our inability to find a systemic or manual solution that would allow us to 'hold' orders pending evaluation." The email further stated that Practice Compliance "would prefer to move all of the Control drug business out of 6001 and to McKesson until the KNAPP solution is in place."

688. However, Walmart did not move its controlled-substance business from DC 6001 to McKesson, instead continuing to use KNAPP and operate a system that Walmart knew would lead it to fail to flag and report suspicious orders.

689. The "Overview of SOM Project Progress" listed specific deficiencies with KNAPP, noting the following:

- "[DC] 6001 had very limited ability to monitor orders – KNAPP does not include monitoring functionality"; and
- "System (Reddwerks or KNAPP) did not allow alerted orders to be 'held' pending evaluation."

690. Because KNAPP did not enable Walmart to hold an order while evaluating that order, Walmart routinely shipped suspicious orders without evaluating them and without reporting them to DEA. In fact, during this time, DC 6001 reported no suspicious orders at all.

f. Walmart knew that it was often not documenting its evaluation of flagged orders, which deprived it of crucial information needed to assess subsequent orders.

691. Prior to July 2014, Walmart had no formal policy requiring it to document its evaluation of orders of interest.

692. Starting in July 2014, Walmart's SOM policy required compliance personnel to evaluate flagged orders and then document those evaluations.

693. Under Pharmacy Manual 21-402 (July 2014), Walmart's evaluations of flagged orders were to be documented using the "Order of Interest Evaluation Form." The policy stated that "[a]ll documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years."

694. Likewise, Walmart's Practice Compliance division adopted a policy in January 2015, referred to as "Controlled Substances Suspicious Order Monitoring," which required Walmart to "document the final conclusion of the evaluation" and "retain documentation of any reports made to the DEA and state agencies."

695. However, prior to 2015, Walmart failed to follow these policies.

696. Walmart recognized this flaw with its SOM system. The October 2014 internal presentation noted that there was "[n]o defined process for tracking why DC cuts or clears specific orders." Likewise, the "Overview of SOM Project Progress" acknowledged that Walmart had "[n]o process for documenting order evaluations or reporting decisions."

697. In those instances when Walmart conducted some due diligence on flagged orders, it often did not record the factual information it may have gathered about the order or the conclusion it made as to whether or not the order was suspicious.

698. For example, from June 26, 2013, through July 31, 2015, Walmart shipped tens of

thousands of weekly orders of Schedule II controlled substances and Schedule III narcotics that exceeded Walmart's own established thresholds, and it did so without documenting facts about those shipments necessary to determine whether those orders or future orders from the same pharmacies were suspicious.

699. Because Walmart did not maintain these records, Walmart compliance personnel charged with scrutinizing and determining whether an order from one of its more than 5,000 pharmacies was suspicious lacked the necessary facts to complete their important gatekeeping role with respect to other orders.

2. From August 2015 through November 2017, Walmart adopted a modified system for flagging and reporting suspicious orders, but it knew this system still failed to flag many suspicious orders.

700. As explained above, Walmart recognized the extensive flaws with its SOM program and the limitations of the Reddwerks and KNAPP systems that Walmart used for suspicious order monitoring.

701. Walmart attempted to address the flaws with a few modifications to its existing Reddwerks system.

702. Walmart hired a consulting firm, Mu Sigma, to review a statistical methodology for identifying suspicious orders that Walmart had designed on its own. Walmart's proposed statistical methodology would implement pharmacy-specific and drug-specific thresholds to replace the 20-bottle and 50-bottle thresholds that Walmart had been using in Reddwerks.

703. Mu Sigma reviewed Walmart's proposed revisions to its SOM system and identified several flaws with the proposed statistical methodology. According to a January 2014 Mu Sigma report to Walmart, the "shortcomings" in Walmart's proposed approach included an inability to flag patterns over time and one-size-fits-all minimum thresholds.

704. Mu Sigma also proposed a more effective methodology than Walmart's proposed approach.

705. Walmart rejected Mu Sigma's proposed approach in part due to cost. In March 2014, K.S., a Senior Manager for Logistics, expressed, "[Mu Sigma] quoted us $185,000 for the work which, I think, is ridiculous."

706. That year, Walmart reported operating profit of approximately $27 billion.

707. In or about August 2015, Walmart implemented the statistical methodology that Mu Sigma had informed Walmart was flawed.

708. Walmart continued to use this modified system from approximately August 2015 through November 29, 2017.

a. Despite the modifications to Reddwerks, many of the same flaws remained.

709. Walmart's modifications to Reddwerks failed to fix many of the serious defects from its prior SOM program.

710. Walmart's modified SOM program still failed to flag orders of an unusual frequency or unusual pattern, much less report those kinds of unusual orders.

711. Walmart's modified SOM program continued to fail to report orders from pharmacies that had reported incidents of diversion to its compliance team and others at the company.

712. Walmart's modified SOM program still did not consider whether a pharmacy was ordering the same controlled substance of the same drug strength, but with multiple NDCs. On October 31, 2017, G.C., Walmart's Senior Director for U.S. Ethics and Compliance, acknowledged this failure in Walmart's system: "The other note around Size, Frequency and Pattern is that under … [Reddwerks] we had thresholds based on each NDC number and not drug strength. This means that someone could order Hydro/Apap 500/325 from 5 different NDC

numbers and that would not create an alert." As noted above, this system defect permitted pharmacies to place orders well beyond the size thresholds without those orders ever being flagged.

713. In addition, Walmart's modified SOM program, when determining whether an order placed with a Walmart distribution center was suspicious, continued to ignore at least hundreds of thousands of orders that its pharmacies placed with independent distributors.

714. Even as late as May 2017, Walmart had the same lack of visibility into orders that Walmart-branded pharmacies placed directly with McKesson. In a May 3, 2017, email, M.J. discussed the rollout of a new project that would "reduce the number of orders going directly to McKesson from the pharmacy. Those direct to McKesson orders limit our ability to get full visibility to what pharmacies order and this project will be very helpful to us."

715. As a consequence of these continuing problems with its SOM system, Walmart failed to report a remarkably large number of suspicious orders to DEA, in violation of the law.

b. Walmart continued to fail to report unusually large orders.

i. Walmart used average order sizes to set thresholds in the midst of the ongoing opioid epidemic.

716. In mid-2015, Walmart changed the Reddwerks thresholds that it used to flag unusually large orders from its pharmacies.

717. Walmart modified its prior approach of applying uniform numeric thresholds to its pharmacies' orders (i.e. the 20-bottle threshold for Schedule II drugs and the 50-bottle threshold for Schedule III, IV, and V drugs). Instead, it imposed pharmacy-specific, drug-specific, weekly thresholds.

718. To set these new thresholds, however, Walmart chose a flawed approach that would flag suspicious orders only in the rarest of instances. For pharmacies that typically

ordered large quantities of controlled substances, Walmart flagged only orders that were more than three standard deviations from that pharmacy's average order size for that drug. For pharmacies that typically ordered smaller quantities of controlled substances, Walmart flagged only orders that were more than three standard deviations from the average order size of all of Walmart pharmacies' orders for that drug.

719. Walmart adopted this approach despite knowing that it was likely to cause Walmart not to flag many orders that were outliers. In early 2014, Mu Sigma, the consulting firm working with Walmart to validate its proposed new methodology, had warned Walmart that Walmart's approach might not flag some unusually large orders.

720. Also, in setting pharmacy-specific thresholds, Walmart chose baselines that were already flawed. Walmart used pharmacy averages based on orders from a 52-week period during a time when, as Walmart was well aware, the opioid epidemic was raging across the country.

721. Had Walmart lawfully rejected and reported suspicious orders before it modified the Reddwerks system, then these order averages would have been lower. But by relying on already excessive orders to calculate a pharmacy's average order, Walmart created an inflated average that masked the suspicious nature of those—and subsequent—orders.

722. Walmart's decision to set thresholds for pharmacies based on inflated pharmacy averages caused it to continue to fail to report suspicious orders.

ii. Walmart's minimum threshold was too high to flag orders that were unusually large for some pharmacies.

723. As described above, the modified Reddwerks system set pharmacy-specific, drug-specific order-size thresholds based on pharmacy averages.

724. The lowest-possible threshold for any controlled substance was 2,000 dosage units per week. Walmart had simply decided that the minimum threshold for flagging an order—

no matter which pharmacy had placed the order and how small that pharmacy's average order plus three standard deviations was—would be 2,000 dosage units per week.

725. For many of Walmart's pharmacies, the 2,000-unit minimum threshold for triggering suspicious order monitoring was far too high to enable Walmart to flag all the orders that were unusually large.

726. Some pharmacies, for instance, typically ordered far below 2,000 dosage units of a particular drug in any given week. This minimum threshold meant that those pharmacies could place an order for an unusually large quantity *for that pharmacy* without that order ever being flagged.

727. As a result of the 2,000-unit minimum threshold, Walmart failed to report aberrant order sizes for those pharmacies that typically ordered smaller amounts of drugs.

iii. Walmart continued to cut unusually large orders and failed to report them to DEA, despite knowing it was unlawful to do so.

728. Walmart continued to manipulate its SOM program in a manner that avoided reporting unusually large orders to DEA.

729. During this period, for some orders that exceeded size thresholds, Walmart continued to "cut," i.e. reduce the size of, those orders, without reporting the initial order to DEA, and then shipped the reduced order.

730. Walmart engaged in cutting orders on a routine basis. For example, over the course of four separate weeks in the fall of 2015, Walmart cut and shipped more than 50 orders without ever reporting these orders to DEA. In another example, Walmart cut at least 40 orders placed between December 7, 2015, and December 16, 2015, and did not report those orders to DEA.

731. Sometimes, Walmart recorded in Archer that it was not filling the original order,

but instead cut the order down to the maximum threshold amount, without further explanation. In other words, Walmart's response to an unusually large order was to ship to the pharmacy the largest amount that was consistent with the threshold—without any apparent investigation of the unusually large order and without reporting the order to DEA.

732. For instance, on September 24, 2015, Store 3633 in Waynesboro, Pennsylvania, placed an order for 12 bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's SOM system and went to the home office for evaluation. Home office personnel called the pharmacy at Store 3633, which in turn related that the pharmacy "just wanted to receive the weekly threshold." On September 24, 2015, Walmart's home office "cut" the order down to 11 bottles. Walmart never reported the initial suspicious order of 12 bottles to DEA. The "reason code" for the cut order in Reddwerks was listed simply as "Error-System(POS)."

733. The next day, on September 25, 2015, Store 3633 placed an additional order for two bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's SOM system and went to the home office for evaluation. Walmart's home office "cut" the order down to zero bottles. Walmart never reported the suspicious order of two bottles to DEA. The "reason code" for the cut order in Reddwerks was listed as "Error-System(POS)."

734. The same day, Walmart took the same approach with an order from a different pharmacy. On September 25, 2015, Store 2281 in West Mifflin, Pennsylvania, placed an order for nine bottles of buprenorphine HCL 8mg. The order was flagged in Walmart's SOM system and went to the home office for evaluation. Home office personnel called Store 2281, which in turn related that the pharmacy "would only like to receive the weekly threshold amount." On September 25, 2015, Walmart's home office "cut" the order down to four bottles. Walmart never reported the suspicious order of nine bottles to DEA. The "reason code" for the cut order

in Reddwerks was listed as "Error-System(POS)."

735. At other times, Walmart would record in Archer that the original order was a "mistake" or "error," without any explanation of the nature of the alleged mistake or error.

iv. Walmart sometimes "canceled" or rejected flagged orders, but failed to report those orders to DEA.

736. Sometimes, Walmart "canceled" or rejected orders that Walmart had flagged for unusual size, without filing a suspicious-order report with DEA. There were many times when Walmart would simply reject an order because the order exceeded thresholds.

737. Over the course of four separate weeks in the fall of 2015, Walmart rejected more than 30 orders. Walmart did not file a suspicious-order report for any of these rejected orders.

738. By way of another example, on December 16, 2015, Store 10 in Tahlequah, Oklahoma, placed an order for 17 bottles of hydrocodone acetaminophen 10/325mg. The pharmacy's threshold for this drug was 50 bottles. Because Store 10 had already ordered 41 bottles that week, the order was flagged as exceeding the threshold. Walmart, after evaluating the order, rejected the order and did not report it to DEA.

c. Walmart set hard limits for pharmacies that had already placed suspicious orders—then disregarded those hard limits and failed to report the orders.

739. Another problem with Walmart's SOM system during this time period was that Walmart, after the submission of a suspicious-order report to DEA, allowed its pharmacies to exceed hard limits that Walmart had imposed on the pharmacies' future orders for certain controlled substances.

740. In those rare instances when Walmart filed a suspicious-order report with DEA for an unusual order placed by a pharmacy, Walmart would sometimes put the pharmacy on a "remediation plan." When a Walmart pharmacy was placed on a remediation plan, Walmart would often reduce the size threshold for the particular drug that had been the subject of the

suspicious-order report. Walmart accomplished this reduction by assigning the pharmacy a weekly hard limit for that drug. The duration of the remediation plan was usually one to two months.

741. Walmart distribution centers often blatantly disregarded the weekly hard limit set in remediation plans.

742. For example, Walmart placed Store 2530 in Rutland, Vermont, on a two-month remediation plan following the March 2, 2017, placement of a suspicious order of 23 bottles of buprenorphine HCL 8mg, an order that brought that pharmacy's weekly total to 65 bottles. The remediation plan limited Store 2530 to a weekly hard limit of 50 bottles for this drug through May 5, 2017. However, during two separate weeks over the course of the remediation period, Walmart shipped 71 bottles and 67 bottles, respectively, to Store 2530 without reporting these orders to DEA.

743. Store 2530 exceeded its remediation-plan hard limit for two additional weeks by placing buprenorphine HCL 8mg orders fulfilled by both McKesson and Walmart. Over a one-week period in April 2017, Walmart shipped 50 bottles of buprenorphine HCL 8mg to Store 2530, and McKesson shipped two bottles, for a total of 52 bottles, exceeding the remediation plan hard limit by two bottles. During the last week of Store 2530's remediation plan in May 2017, Walmart shipped 50 bottles of buprenorphine HCL 8mg to the pharmacy, and McKesson shipped 106 bottles. The total of 156 bottles in that one week was more than three times Store 2530's remediation-plan hard limit of 50 bottles.

744. In another example, following an August 23, 2017, suspicious order of 42 bottles of hydrocodone-acetaminophen 10/325mg for a total weekly order of 79 bottles, Walmart placed Store 130 in Muskogee, Oklahoma, on a remediation plan for hydrocodone-acetaminophen

10/325mg. The remediation plan limited Store 130 to a weekly hard limit of 50 bottles of hydrocodone-acetaminophen 10/325mg from August 25, 2017, through October 20, 2017. Yet during at least one week of the remediation plan, Walmart shipped 61 bottles to the pharmacy, ignoring the 50-bottle weekly limit without reporting this order to DEA.

C. Walmart's flawed approach to monitoring pharmacy orders resulted in a failure to report at least hundreds of thousands of suspicious orders.

745. All of the significant shortcomings from the initial Reddwerks system and the modified Reddwerks system rendered Walmart's SOM program ineffective and, as a result, Walmart failed to report suspicious orders to DEA as required by law.

746. The United States estimates that from June 26, 2013, through November 29, 2017, Walmart shipped approximately 15.2 million orders of Schedule II controlled substances and Schedule III narcotics to its own pharmacies. This figure does not include any other Schedule III controlled substances, or any Schedule IV and Schedule V controlled substances. The United States estimates that from June 26, 2013, through November 29, 2017, Walmart shipped approximately 37.5 million Schedule II, III, IV and V orders to its pharmacies.

747. During the same time period, Walmart reported only 204 suspicious orders to DEA—an infinitesimal percentage.

748. By comparison, McKesson, the independent distributor that served as the back-up distributor to Walmart-branded pharmacies, received far fewer orders from Walmart's pharmacies but reported to DEA more than 13,000 suspicious orders from Walmart pharmacies between June 26, 2013, and November 29, 2017.

D. Walmart's failure to report suspicious orders deprived Walmart of the opportunity, during the opioid epidemic, to timely address potentially unlawful conduct.

749. Walmart's failure to report suspicious orders not only violated the law, but also

inhibited Walmart's ability to timely investigate the suspicious orders and uncover potentially unlawful conduct.

750. Before reporting suspicious orders to DEA, Walmart first had to identify the suspicious orders for itself. The regulation explains that the distributor must design and operate a system "to disclose *to the registrant* suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b) (emphasis added).

751. If Walmart had properly identified suspicious orders in the first place, as required by the regulation, steps could have been taken to investigate the orders.

752. For example, under a policy Walmart adopted in 2015, once it identified a suspicious order, it would develop a "remediation plan" for the pharmacy that placed the suspicious order. Under this policy, Walmart would conduct an investigation into the reasons for the unusual order. This investigation could include engaging Walmart's Global Investigations group to open a review of the ordering pharmacy and requiring an on-site visit by Health and Wellness Operations to conduct a review and additional training at the pharmacy. The policy required Walmart to "document the final conclusion of the evaluation" and "retain documentation of any reports made to the DEA and state agencies." Also, under the policy, Walmart could increase oversight of future orders from the pharmacy.

753. If Walmart had complied with its obligation to report suspicious orders, it would have investigated the reasons for those orders and initiated remediation plans. It thus could have taken steps that might have led to the timely prevention of unlawful, improper, or dangerous conduct. For example, Walmart could have discovered that the unusually high demand for a controlled substance at a particular pharmacy was resulting from dispensing at that pharmacy for a pill-mill prescriber.

754. For the massive number of suspicious orders that Walmart never even reported, Walmart did not institute remediation plans to inquire into the orders.

755. When Walmart filled suspicious orders, Walmart's approach allowed dangerous controlled substances to enter the market. Even in those circumstances where Walmart recognized that certain orders were "suspicious" after those orders had already been shipped to its stores, Walmart's failure to report those orders and take other remedial steps allowed the ordered drugs to "enter the market." As a Senior Manager for Logistics wrote in an August 20, 2014, email, "[t]he alternative to pulling the order back is to simply continue to follow the process we have today. We can add further evaluation of orders after shipment but, if we see an issue that suggests that product shouldn't have been shipped, we just leave it at the store and let it enter the market. Given the choices, [having the store] ship … the product back feels like the more socially responsible approach, but the [Distribution Center] will do whatever leadership wants them to do."

756. Walmart's systematic failure, for years, to comply with its legal obligation to report each of its suspicious orders thus created a major obstacle to efforts to combat the opioid epidemic.

757. Walmart also financially benefited from these violations of law. Walmart chose to avoid the expense of creating and implementing a proper program for monitoring and reporting suspicious orders. For example, Walmart avoided the expense of creating and implementing a remediation plan for each suspicious order, which could have imposed burdens on Walmart and might also have uncovered improper activity that Walmart would have to remediate. Likewise, Walmart avoided the expense of paying for adequate numbers of compliance personnel. Most critically, Walmart profited by providing its pharmacies with

unusually large quantities of controlled substances to sell, and from selling other products to customers who came to Walmart stores only because Walmart pharmacies would readily provide these controlled substances.

758. In sum, Walmart chose, for years, to disregard a well-established legal obligation on a systematic basis and a huge scale. In doing so, Walmart substantially benefited itself while contributing to the nationwide opioid epidemic.

CLAIMS FOR RELIEF

FIRST CLAIM

(For civil penalties and other relief, based on violations of 21 U.S.C. §§ 842(a)(1) & 829 and 21 C.F.R. § 1306.04(a))

759. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

760. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.04(a), because it, through its agents and employees, knowingly dispensed controlled substances pursuant to prescriptions that were either not issued in the usual course of professional treatment, not for a legitimate medical purpose, or both.

761. Walmart violated these provisions on multiple occasions, with the precise number of violations to be established at trial.

762. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

763. The United States also requests that the Court issue an order granting appropriate injunctive relief tailored to restrain Walmart's violations of 21 U.S.C. § 842. *See* 21 U.S.C. § 843(f).

SECOND CLAIM

(For civil penalties and other relief, based on violations of 21 U.S.C. §§ 842(a)(1) & 829 and 21 C.F.R. § 1306.06)

764. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

765. During the Dispensing Violations Period, from June 26, 2013, to the present, Walmart repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.06, because it, through its agents and employees, did not adhere to the usual course of the professional practice of pharmacy in filling prescriptions for controlled substances.

766. Walmart violated these provisions on multiple occasions, with the precise number of violations to be established at trial.

767. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

768. The United States also requests that the Court issue an order granting appropriate injunctive relief tailored to restrain Walmart's violations of 21 U.S.C. § 842. See 21 U.S.C. § 843(f).

THIRD CLAIM

(For civil penalties, based on violations of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b))

769. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

770. During the Distribution Violations Period, from June 26, 2013, through November 29, 2017, Walmart refused or negligently failed to report suspicious orders to DEA, in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b).

771. Walmart violated 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b) on multiple occasions, with the precise number of violations to be established at trial.

772. For each violation, Walmart is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(B).

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests judgment to be entered in its favor and against Walmart as follows:

a. Awarding a sum equal to civil penalties to the maximum amount allowed by law;

b. Granting injunctive relief to address and restrain Walmart's violations of law; and

c. Granting the United States such further relief as the Court may deem proper.

Respectfully submitted,

Dated: October 7, 2022

MICHAEL D. GRANSTON
Deputy Assistant Attorney General

/s/ Gustav W. Eyler
GUSTAV W. EYLER
Director
Admitted pro hac
AMANDA N. LISKAMM
Principal Deputy Director
Admitted pro hac
ADAM E. LYONS
Assistant Director
Admitted pro hac
JOSHUA FOWKES
Admitted pro hac
KATHLEEN B. GILCHRIST
Admitted pro hac
KATHERINE M. HO
Admitted pro hac

COLE FINEGAN
United States Attorney for the
District of Colorado

/s/ Kevin T. Traskos
KEVIN T. TRASKOS
AMANDA A. ROCQUE
JASAND P. MOCK
Special Attorneys to the Attorney General
1801 California Street, Suite 1600
Denver, CO 80202
kevin.traskos@usdoj.gov
303-454-0100

U.S. Department of Justice
Civil Division
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
gustav.w.eyler@usdoj.gov
202-307-0066

DAVID C. WEISS
United States Attorney for the
District of Delaware

/s/ Laura D. Hatcher
LAURA D. HATCHER
DYLAN STEINBERG
Assistant United States Attorneys
1313 N. Market Street
Wilmington, DE 19801
laura.hatcher@usdoj.gov
302-573-6277

ROGER B. HANDBERG
United States Attorney for the
Middle District of Florida

/s/ Carolyn B. Tapie
CAROLYN B. TAPIE
Special Attorney to the Attorney General
400 North Tampa Street, Suite 3200
Tampa, FL 33602
carolyn.b.tapie@usdoj.gov
813-274-6000

BREON PEACE
United States Attorney for the
Eastern District of New York

/s/ Elliot M. Schachner
ELLIOT M. SCHACHNER
MEGAN FREISMUTH
Special Attorneys to the Attorney General
271 Cadman Plaza East
Brooklyn, NY 11201
elliot.schachner@usdoj.gov
718-254-7000

MICHAEL F. EASLEY, JR.
United States Attorney for the Eastern District
of North Carolina

/s/ C. Michael Anderson
C. MICHAEL ANDERSON
ANDREW KASPER
Special Attorneys to the Attorney General
(pending)
150 Fayetteville Street, Suite 2100
Raleigh, NC 27601
michael.anderson7@usdoj.gov
919-856-4619